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Initial Feedback on Sperm Donation for Single Women at Rouen University

Chloé Douessin

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UFR DE SANTE ROUEN NORMANDIE

Année 2023-2024

**THESE POUR LE
DOCTORAT EN MEDECINE**

(Diplôme d'Etudes Spécialisées en Gynécologie Médicale)

Par

DOUESSIN Chloé

Née le 13 Janvier 1995 à Meulan en Yvelines

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**Initial Feedback on Sperm Donation for Single Women at
Rouen University**

Président du jury : Mr le Professeur Hervé LEFEBVRE

Directrice de thèse : Mme le Professeure Nathalie RIVES

Membres du jury : Mme le Docteur Claire Hélène PETROVIC

Mme le Docteur Romane LEVADE

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Par délibération en date du 3 Mars 1967, la faculté a arrêté que les opinions émises dans les dissertations qui lui seront présentées doivent être considérées comme propres à leurs auteurs et qu'elle n'entend leur donner aucune approbation ni improbations.

SERMENT D'HIPPOCRATE

Au moment d'être admis(e) à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux. Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité. J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences. Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences. Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis(e) dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu(e) à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs. Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité. Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré(e) et méprisé(e) si j'y manque.

Remerciements

Aux membres du Jury

A Monsieur le Professeur Hervé Lefebvre, merci à vous d'avoir accepté de présider mon jury de thèse. Je fais partie de ces dernières promotions que vous avez accueillies, avec toute votre humilité et bienveillance, en tant que coordinateur du DES de gynécologie médicale. Je vous remercie pour l'engagement pris pendant toutes ces années pour cette belle spécialité.

A Mme le Professeure Nathalie Rives, cela a été un honneur de mener à bien ce travail de thèse sous votre supervision et encadrement. Merci à vous d'avoir cru en moi et dans mon travail. Je suis très reconnaissante de votre implication, tant dans nos travaux de thèse, que dans la gestion et le développement de notre spécialité qui ne demande qu'à briller.

A Mme le Docteur PETROVIC Claire Hélène, notre première gynécologue médicale universitaire. Quel bel exemple tu donnes à toutes les générations qui te suivent. Un exemple de force et de ténacité, en menant de front à la fois cette vie professionnelle riche en nous organisant des sessions de cours/bibliographies, permettant échanges et apprentissages au sein de notre groupe, et cette nouvelle vie personnelle, de jeune maman. Merci de nous montrer qu'avec de la détermination, tout est possible.

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A ma famille

A vous, papa et maman,

Enfin votre aînée, votre grande fille de bientôt 30 ans, est diplômée... il était temps ! Et ce n'est pas n'importe quel diplôme que je rapporte à la maison, mais celui de Dr, le premier de la famille Douessin (et Feuille !). Je vous avoue être très fière de pouvoir apporter ce mérite à notre famille, et j'espère que vous l'êtes aussi aujourd'hui. Tout ce chemin accompli n'aurait pas été possible sans vous, sans votre soutien moral et un peu financier aussi (il faut se le dire !). J'aimerais pouvoir à l'avenir, autant contribuer au projet professionnel de mes futures enfants, que vous l'avez fait pour Louna, Mathéo et moi. Merci pour tout.

A toi, Louna, ma sœur,

Je sais que, malgré moi, je ne t'ai pas toujours rendu facile la place de deuxième enfant dans notre jeunesse, et je m'en excuse. Malgré tout, j'espère avoir pu t'aider, au moins un peu, et que cela a pu influencer ton très beau parcours. Tu as su faire les bons choix, aux bons moments, même si cela n'était pas évident, et tu as réussi brillamment.

Sache que je suis très fière de la jeune femme que tu es aujourd'hui, bien plus indépendante, entrepreneuse et sur d'elle que je ne le suis.

A toi Mathéo, mon frère,

Presque 14 années nous séparent, on pourrait presque parler d'une génération. Je t'ai vu devenir ce beau jeune homme qui est aujourd'hui à l'aube de ces premiers grands choix professionnels, et tu me vois devenir docteur. J'espère durant toutes ces années avoir été une forme d'exemple pour toi. Un exemple que le travail paie.

Sache que peu importe les choix que tu feras et les chemins que tu prendras, je serai toujours là pour t'accompagner.

A toi Mickaël, mon chéri,

Il y a quelques semaines nous avons fêté notre première décennie ensemble, et quelle décennie. Tu m'a vu gravir au cours de toutes ces années cette grande chaîne montagneuse que sont les études de médecine. D'étudiante en première année, à externe en médecine, puis interne et enfin Docteur en gynécologie médicale. Bien que j'ai souvent consacré mon temps à ma vie professionnelle, au dépend de la nôtre, tu as toujours été là pour moi, pour me soutenir dans les bons comme les mauvais moments, et je ne t'en remercierai jamais assez. J'ai à cœur à présent de penser plus à nous et aux beaux projets que nous allons entreprendre, je t'aime.

A vous, papy et mamie,

Merci d'avoir réalisé tous ces kilomètres pour venir me voir aujourd'hui. Je mesure la chance de vous avoir à mes côtés pour ce grand moment, et cela me rend si heureuse. On ne vous remerciera jamais assez avec Louna et Mathéo, des souvenirs d'été passés chez vous et de l'amour que vous nous avez donné.

A ma belle-famille, Fanja, Eric, Lucas et Alex

Vous m'avez accueilli dans votre foyer avec toute votre générosité, et avez toujours pris la peine de suivre mon long parcours et de m'en féliciter, merci à vous pour toutes ces attentions. J'essaierai de toujours vous le rendre au mieux.

A mon beau-frère, Nathan,

Merci d'être cette personne qui apporte toujours bonne humeur et rigolade à nos repas de famille. Je suis reconnaissante de l'amitié fraternelle qui nous lie tous ensemble lors de ces bons moments, et espère qu'elle perdurera le plus longtemps possible.

A tous mes collègues et co-internes en gynécologie médicale

Quel mérite de pouvoir évoluer et échanger dans un groupe comme celui-ci, plein de femmes (et un homme !) plus talentueuses les unes que les autres.

A toi, ***Alix***, ma première co interne de gynécologie médicale. Je ne sais pas si j'en serai ici aujourd'hui sans toi. Cet été 2021 a été une période extrêmement difficile pour moi, tant sur le plan physique que psychologique, à se demander si autant de pleurs et de sommeil perdu en valait la peine. Tu as été un repère dans cette tempête, une épaule sur laquelle j'ai pu

m'adosser et une oreille à qui j'ai pu me confier. Merci d'avoir été là, même si tu me devras éternellement, sache le, un test PCR COVID.

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Liste des abbreviations:

AFC : Antral Follicules count

AMH : Anti Mullerian Hormone

ART : Assisted Reproductive
Technology(ies)

BMI : Body Mass Index

CBRC : Cross-Border Reproductive Care

CC : Clomiphene Citrate

CDR : Cumulative Delivery Rate

CECOS : Centre d'Etude et de
Conservation des Œufs et du Sperme
Humain

COH : Controlled Ovarian
Hyperstimulation

CPR : Clinical Pregnancy Rate

CuPR : Cumulative Pregnancy Rate

DET : Double embryo transfer

eSET : elective Single Embryo Transfer

ESHRE : European Society of Human
Reproduction and Embryology

FET : Frozen Embryon transfer

FSH : Follicules Stimulating Hormone

GW : Gestational Week

GnRH : Gonadotrophin Releasing
Hormone

HC : Heterosexual(s) Couple(s)

hCG : human Chorionic Gonadotropin

HIV : Human Immunodeficiency Virus

hMG : human Menopausal Gonadotrophin

HPV : Human Papilloma Virus

ICM : Internal Cell Mass

ICSI : Intra Cytoplasmic Sperm Injection

INSEE : National Institute for Statistic and
Economic Studies

IUI : IntraUterine Insemination

IVF : In Vitro Fertilization

LBR : Live Birth Rate

LC : Lesbian Couple(s)

LH : Luteinizing Hormone

MAR : Medically Assisted reproduction

MCM : Multidisciplinary Consultation
Meeting

MRI : Magnetic Resonance Imaging

NOA : Non-obstructive Azoospermia

PCOS : PolyCystic ovary Syndrome

PGD : Pre-implantation Genetic Diagnosis

PR : Pregnancy Rate

OHSS : Ovarian Hyperstimulation Syndrome

SW : Single Women

TESE : Testicular Sperm Extraction

WHC : Women in Heterosexual Couple

Initial Feedback on Sperm Donation for Single Women at Rouen University

ABSTRACT

PURPOSES : We aimed to study the main characteristics and motivations of single women (SW) who have registered for sperm donation at Rouen University Hospital and to compare results of their ART cycles with those of heterosexual couples (HC).

PARTICIPANTS/MATERIALS, SETTING, METHODS : We conducted an observational, retrospective, monocentric study at the Reproductive Biology Laboratory-CECOS of the Rouen University Hospital, on all 386 SW and 67 HC registered for sperm donation between August 2021 and December 2022. Of these, 105 SW and 34 HC have started ART cycle. To ensure a more robust comparison of the ART cycle's results, we also included 41 HC who were treated for sperm donation at our centre between 2019 and the first half of 2021. We analysed all the medico-social and motivational characteristics of the women in the study, as well as the clinical pregnancy rate, the live birth rate and the miscarriage rate.

MAIN RESULTS : SW were older at the time of registration and at the start of ART cycle, and their ovarian reserve was lower than that of women in HC. Their main reasons for requesting sperm donation were the biological clock and the lack of a suitable partner to build a family project. All ART combined, there was no significant difference in clinical pregnancy rate or miscarriage rates between SW and HC.

CONCLUSIONS : Although SW were older and had a lower ovarian reserve, the results of their ART cycles were no worse than those of HC in our study, apart from any adjustment for age. However, these analyses need to be continued over time and space, so that they can be extrapolated and compared with the initial results of lesbian couples.

KEY WORDS : single women, heterosexual couples, sperm donation care pathway, Biology Laboratory-CECOS, Rouen University Hospital, clinical pregnancy rate, miscarriage rate.

Premier retour d'expérience sur le don de spermatozoïdes chez les femmes seules au Centre Hospitalo-Universitaire de Rouen

RESUME

OBJECTIFS DE L'ETUDE : Etudier les principales caractéristiques et motivations des femmes seules (FS) s'étant enregistrées en vue d'un don de spermatozoïdes au CHU de Rouen, et de comparer les résultats de leurs premières tentatives par rapport aux couples hétérosexuels (CH).

PARTICIPANTS/MATERIELS ET METHODES : Nous avons mené une étude observationnelle, rétrospective, monocentrique au sein du Laboratoire de Biologie de la Reproduction-CECOS du CHU de Rouen, sur l'ensemble des 386 FS et des 67 CH s'étant enregistrés pour une prise en charge en don de spermatozoïdes entre Aout 2021 et Décembre 2022. Parmi eux, 105 FS et 34 CH ont débuté un cycle de traitement. Afin d'assurer une comparaison plus solide en termes d'effectif pour les résultats des tentatives, 41 CH ayant été pris en charge en don de spermatozoïdes entre 2019 et le 1^{er} semestre 2021 dans notre centre ont été également inclus. Nous avons analysé l'ensemble des caractéristiques médico-sociales et motivationnelles des femmes de l'étude, ainsi que les taux de grossesses clinique évolutive à l'échographie des 6 semaines de grossesse, le taux de naissance vivante et le taux de fausse couche précoce.

PRINCIPAUX RESULTATS : les FS sont plus âgées au moment de l'enregistrement comme au début du 1^{er} cycle de traitement, et leur réserve ovarienne est plus basse que celle des femmes des CH. Leurs principales motivations au don de spermatozoïdes se réfèrent à l'horloge biologique et à l'absence de partenaire adéquat à un projet familial. Toutes techniques confondues, il n'existe pas de différence significative sur le taux de grossesse clinique et de de fausse couche entre les FS et les CH.

CONCLUSIONS : Bien que les FS soient plus âgées et présentent une réserve ovarienne plus faible dans notre étude, en dehors de tout ajustement pour l'âge, les résultats de leurs tentatives ne sont pas moins bon que ceux des CH. Toutefois, il est nécessaire de poursuivre ces analyses dans le temps et l'espace afin de pouvoir les extrapoler, et de les comparer aux premiers résultats des femmes lesbiennes.

MOTS CLEF : femmes seules, couples hétérosexuels, don de spermatozoïdes, Laboratoire de Biologie de la Reproduction-CECOS, CHU de Rouen, grossesse clinique évolutive, fausse couche précoce.

Introduction

In France, sperm donation is regulated by successive bioethics laws of 1994, 2004, 2011 and 2021 (Loi n° 94-654 ; Loi n° 2011-814 ; Loi n° 2011-814). The “Centres d’Etude et de Conservation des Œufs et du Sperme humain” (CECOS) manage gamete and embryo donation in collaboration with clinical assisted reproductive technology (ART) units. The first CECOS was established in Paris in 1973, and there are now 33 CECOS throughout France. From 1973 to 2021, the reference population eligible for sperm donation was primarily heterosexual couples (HC) who were married or in a stable relationship. Male infertility was mainly associated with non-obstructive azoospermia (NOA) or severe semen parameter alterations confirmed after at least two semen analyses. The remaining minority of recipients for sperm donation were HC at risk of transmitting a serious genetic disease to their offspring, which was incurable at the time of diagnosis, or in case of Human Immunodeficiency Virus (HIV) in male partner.

The use of ART has evolved significantly with the introduction of IntraCytoplasmic Sperm Injection (ICSI) (Palermo et al., 1992), micromanipulation methods with sperm washing in HIV serodiscordant couples (Meseguer et al., 2002), and surgical techniques such as conventional or micro Testicular Sperm Extraction (TESE) (Van Peperstraten et al., 2006), as well as genetic screening allowing for Pre-implantation Genetic Diagnosis (PGD) (Li et al., 2020). These advancements have enabled some couples to conceive using their own gametes. Nevertheless, sperm donation remains an essential part of ART. In recent decades, social and political changes have led to the emergence of new populations in need of sperm donation, such as lesbian couples (LC) and single women (SW). Although generally not considered infertile, LC and SW are unable to conceive naturally due to the absence of male gametes. The 2021 revision of the French Bioethics law brought about significant changes. Firstly, ART with gamete or embryo donation was extended to LC and SW, specifying unmarried status instead of the absence of a partner for SW. Secondly, children born after gamete donation can have access to the donor's identifying and non-identifying data upon reaching the age of majority (18 years old in France). Consequently, from 1st September 2022, only adult males and females who consent to the transfer of their identifying and non-identifying data will be eligible to voluntarily donate their gametes. Double gamete donation, previously limited to embryo donation, is now legally not forbidden. Additionally, social egg or sperm freezing,

without a medical indication, is now permitted (Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique, 2021).

However, French LC and SW did not have waited for this legal issue to use third party ART and fulfil their desire to have children. In fact, many of our European neighbours have already permitted these practices, and the number of French patients seeking treatment abroad has increased over time to avoid restrictive French rules. According to Calhaz-Jorge et al., (2020), 18 European countries offer treatment to LC and 30 European countries offer treatment to SW. Cross-Border Reproductive Care (CBRC) is a phenomenon where infertile patients or partners seek or provide reproductive treatment outside their home country. This term was coined by the European Society of Human Reproduction and Embryology (ESHRE) and is widely used in the literature (Pennings et al., 2008). France was one of the top four countries in Europe for CBRC use in 2010, especially in Belgian centres (Shenfield et al., 2010). In 2006, over 2,000 foreign patients received treatment in Belgium, and 80% of ART cycles with sperm donation were performed in French women (Pennings et al., 2009). In 2013, a French study found that 94% of patients who travelled to Belgium for sperm donation were ineligible for ART in France due to their sexual orientation or unmarried status. The main reason for their choice was the proximity of Belgium, particularly for women from north-eastern France (Rozée Gomez & de La Rochebrochard, 2013).

Between the implementation of the new bioethics law in August 2021 and 31st December 2022, almost 15,100 initial consultations were requested nationally for sperm donation by LC and SW. Out of these requests, over 11,000 recipients have undergone the initial consultation, with almost 2,000 cycles of ART performed mostly by SW (53%). A total of 444 pregnancies have progressed beyond 12 weeks of amenorrhoea, and 21 deliveries have been recorded. In comparison, in 2020, 662 children were born in infertile HC through sperm donation. As of December 31st 2022, 5,600 HC, LC and SW were still waiting for sperm donation, which accounts for almost one third of each population (31% HC, 36% LC and 33% SW) (Agence de la biomédecine, cinquième réunion du comité de suivi de bioéthique, unpublished data).

Numerous studies have been conducted to determine the predictors of success in ART using sperm donation. While most of the available data interested intrauterine insemination (IUI), maternal age has been identified as the most significant predictor of pregnancy rate (PR) and Cumulative pregnancy rate (CuPR). Maternal age negatively affected PR, regardless of the group of recipients (LC or SW) or type of ovarian stimulation used (spontaneous ovulation,

ovarian stimulation by Clomiphene Citrate (CC) or by human Menopausal Gonadotrophin (hMG)) (Ferrara et al., 2000, 2002). A Belgian study conducted almost ten years later confirmed these trends with expected cumulative delivery rate (CDR) after 12 cycles of IUI at 87% in the youngest group (20-29 years) and that fell to 52% in the oldest group (40-45 years), regardless of social status (De Brucker et al., 2009). The authors also applied their findings to women who have undergone ICSI. After 6 ICSI cycles, there was a decrease in CDR from 93% in the youngest group to 82% in the oldest group. The difference was more significant when looking at the crude CDR, with 81% in the youngest group and 54% in the oldest group (De Brucker et al., 2014). Additionally, there was no significant difference in CDR between the two techniques used in these women (IUI or primary ICSI without previous IUI). This result was also validated in a population of older women aged 40 and over, after a maximum of 6 IUI cycles or 3 ICSI cycles (De Brucker et al., 2013). However, since all pregnancies in the ICSI group were achieved in the first treatment cycle, it would seem reasonable to choose ICSI as the first option for older women, rather than undergoing several cycles of IUI to optimise their treatment. More, after adjusting for age, there was no significant statistical difference between LC and SW in terms of the number of days of stimulation in the In Vitro Fertilization (IVF) cycle, the total dose of gonadotropins received before oocyte punctures, the number of frozen embryos or cancelled cycles, or the miscarriage rates (Wrande et al., 2022).

Other factors have been suggested as potential predictors of success, particularly for IUI, but the results are often poorly described or confounded in the literature, including the type of ovarian stimulation (Le Lannou, 2007), the number of mature follicles with a mean diameter of at least 15 mm at the time of triggering (Mokdad et al., 2013), smoking history, primary or secondary infertility, and low progesterone levels on day zero of the menstrual cycle (Thijssen et al., 2017).

Establishing personalised care pathways for each woman using available data is a medical and economic challenge. The goal is to ensure maximum access to maternity while limiting associated risks. This is particularly important in France, as it is one of the few European countries where almost all ART-related costs are covered by the national social health care insurance system. Prior to the legislative change, a French team proposed algorithms for managing IUI with sperm donation based on patient age and initial ovarian reserve assessment. This proposal was informed by a retrospective analysis of a small cohort of 188

patients. For women under 38 years with a satisfactory work-up, the maximum number of unsuccessful cycles considered acceptable before proceeding to IVF has been set at 4, compared to 3 attempts for older women (Mokdad et al., 2013). In 2020, a retrospective study was conducted at a single British centre and included 8,922 IUI cycles with sperm donation in 3,333 consecutive women from HC, LC and SW recipients. The study concluded that a maximum of 6 cycles is reasonable for women under 40, and 3 attempts up to the age of 42. However, the study did not specify the ovarian reserve of the women (Linara-Demakakou et al., 2020).

Recent studies have compared the results of sperm donation with those of using the partner's sperm in HC. As far as IUI is concerned, in groups of women considered to have a « good prognosis », meaning before the maternal age of 37 years, IUI gives better Live Birth Rate (LBR) results than autologous IUI. The use of donor sperm was found to increase the likelihood of a live birth after IUI treatment, even in the oldest population represented by SW. However, this association was not observed after IVF treatment (Catalini et al., 2023).

The literature lacks a clear description of the SW population. Although they are often noted for their older age compared to other groups, few studies have examined their medical history, particularly their gynaecological history. Furthermore, there is limited research on their motivations for using sperm donation to become mothers and their rate of medical care dropout. For instance, no significant difference in the prevalence of Polycystic Ovary Syndrome (PCOS) has been observed between LC and women in heterosexual couple (WHC) who used IUI with donor sperm. However, the data on SW were not available as they were excluded from the study population (De Sutter et al., 2008). Therefore, the aim of our current study was to provide an initial overview of the social, medical and motivational characteristics of the population of SW who have registered for sperm donation at the Reproductive Biology Laboratory-CECOS of Rouen University Hospital and to compare the initial results of their ART cycles with those of HC, the reference population, in order to better adapt their medical management.

Materials and methods

Study design and setting

This retrospective observational single-center study collected socio-demographic, clinical, and biological data from the patients' electronic medical records (MEDIFIRST software, Montigny-le-Bretonneux, France). SW who contacted the Reproductive Biology Laboratory-CECOS of Rouen University Hospital from August 2021 and December 2022 were eligible for the current study. Women who did not meet any exclusion criteria were allocated a first appointment. Exclusion criteria included women below 18 years or over 45 years of age, already receiving care in a geographical area covered by another Reproductive Biology Laboratory-CECOS in France at the time of enrolment or abroad. The purpose of the first appointment with medical doctor specialist in reproductive medicine or biology was (i) to review the main points of the 2021 bioethics law, (ii) to collect administrative data and medical, surgical, gynaecological, obstetrical and family history, (iii) to complete a questionnaire specific to the SW population regarding their lifestyle, their motivations, and the overall image they have of sperm donation, (iv) to prescribe a complete ovarian reserve assessment including a hormonal serum assessment and ultrasound antral follicle count (AFC) at the beginning of the menstrual cycle, ideally without hormonal contraception, hysterosalpingography and infectious disease serological assessment (hepatitis B and C, HIV and syphilis). After the initial appointment, two mandatory interviews were scheduled with our psychology staff.

Then, the files were presented at a monthly Multidisciplinary Consultation Meeting (MCM) attended by reproductive biologists, gynaecologists, psychologists and nurses from the medically assisted reproduction (MAR) unit. A second appointment was arranged to inform the patient about the MCM decision about the third party ART (refusal, sperm donation, double gamete donation or embryo donation), discuss the next steps including (v) sign all necessary informed consents to perform ART with gamete or embryo donation, (vi) conduct a comprehensive family genetic investigation, (vii) prescribe additional biological or radiological explorations if necessary and (viii) perform a gynecological examination with vaginal screening samples for bacteriological, mycological, and virological purposes, as well as a simulated insemination or embryo transfer using an empty flexible catheter. A third appointment was scheduled to provide and explain the protocols of ovarian stimulation and prescriptions for the planned treatments.

The pathway for the registered HC population remains largely unchanged over the same period. However, an additional exclusion criterion was added for the current study, namely HC consisting of a trans- gender man and cis- gender woman. The study recorded the male's urological history, semen parameters and karyotype, if performed, while the female partner was not required to complete a specific questionnaire as for SW. For psychological interviews, each member of the HC must attend a separate appointment in case of first parental project with sperm donation. For subsequent projects, a single joint appointment was proposed to the HC. To ensure a fair comparison between SW and HC, because the number of SW who started sperm donation attempts during the study period was higher compare to HC, we searched data from the registers of HC's ART cycles with sperm donation from previous years (first half of 2021, 2020 and 2019) in our Reproductive Biology Laboratory-CECOS. Each HC was considered only once, based on the most recent parental project, in the case of multiple parental projects over time.

Ovarian stimulation

A personalized ovarian stimulation protocol was established based on the patient's clinical and biological profile, including age, Body Mass Index (BMI), ovarian reserve, and any response to previous ovarian stimulation, as well as the chosen technique (IUI, ICSI, frozen embryo transfer). Several protocols are available for ART that require Controlled Ovarian Hyperstimulation (COH) with daily subcutaneous injections of gonadotropins, mainly including a Gonadotrophin Releasing Hormone (GnRH) agonist protocol or an antagonist protocol. For frozen embryo transfer (FET), the choice was between a gonadotropin-stimulated cycle or an artificial cycle with oral or vaginal exogenous oestrogen therapy (Provames[®], Norgine, Rueil-Malmaison, France) or transdermal oestrogen therapy (Dermestril[®], Viatrix Medical, Courbevoie, France). Stimulation was regularly monitored using transvaginal ultrasound to count and measure the number of growing antral follicles, as well as to measure the thickness and appearance of the endometrium. Blood samples were also collected to check serum levels of 17 β estradiol, Luteinizing Hormone (LH) and progesterone, which allowed for adaptation of the protocol.

Intrauterine Insemination (IUI)

To trigger ovulation during IUI cycles, antral follicles with an average diameter of 15 mm or greater at ultrasound examination were limited to one or two. If three or more antral follicles

with an average diameter of 12 mm or greater were present during ultrasound examination, the IUI cycle was cancelled due to the high risk of multiple pregnancy. Recombinant human Chorionic Gonadotropin (hCG) (Ovitrelle[®], Merck Serono, Lyon, France) was injected for triggering, followed by a single IUI 36 hours later. One or two frozen sperm straws were thawed depending on the number of motile spermatozoa per straw. After thawing spermatozoa were selected after discontinuous density gradient using a 2-layer gradient of 40% and 90% fractions of Puresperm[®] (PureSperm 100[®], JCD, La Mulatière, France) diluted in IVF medium[®] (Coopersurgical, Limonest, France). After the gradient centrifugation, the 90% fraction was washed with IVF medium[®] (Coopersurgical, Limonest, France) by centrifugation at 2000 rpm for 10 minutes. The final pellet was resuspended in 0.5ml of IVF medium[®] (Origio) and incubated at 37°C with 5% CO₂ before insemination.

Oocytes collection, embryo selection and transfer

For ICSI cycles, at least three antral follicles with a mean diameter of 15 mm or greater at ultrasound examination were necessary to triggering ovulation, often with hCG (Ovitrelle[®], Merck Serono, Lyon, France), as for IUI cycles, but occasionally with a GnRH agonist (Decapeptyl[®], Ipsen Pharma, Boulogne-Billancourt, France) if there was a high risk of ovarian hyperstimulation syndrome (OHSS). Thirty-six hours after triggering, patients were scheduled for oocyte collection in the operating room. The procedure was performed by transvaginal ultrasound-guided follicular aspiration under either general or local anaesthesia. Oocytes for ICSI underwent mechanical and enzymatic decoronization (Hyadase[®], Origio, France).

After discontinuous density gradient performed as mentioned above, frozen-thawed spermatozoa were selected for ICSI into a drop of polyvinylpyrrolidone (PVP[®], Origio, France) before being immobilized by a flagellum lesion using an injection pipette (ICSI Micropipets[®], Origio, France). Mature oocytes were microinjected using micromanipulators (Eppendorf, Germany) mounted on an inverted microscope (DMIRB1, Leica, France). The oocytes were cultured at 37°C with 5% CO₂ with G-series culture medium (Coopersurgical, France). Normal fertilization was determined 16-20 hours after ICSI by the presence of two pronuclei. The fertilization rate (%) was estimated by the ratio between the number of fertilized oocytes and the number of microinjected mature oocytes. Subsequently, the quality of the embryos obtained was periodically evaluated, from the early stages (days 2 and 3 of development) to the blastocysts stage at days 5 and 6 of development. Embryo morphology at

day 2 (D2) was assessed on the basis of the number of blastomeres, blastomere size, fragmentation rate and the presence of multinucleated blastomeres, according to the classification of the European Society of Human Reproduction and Embryology (ESHRE) (Alpha Scientists In Reproductive Medicine et Eshre Special Interest Group Embryology 2011). Embryos with four regular blastomeres and less than 20% fragmentation were defined as top-quality embryos (type A). In addition, at day 5 (D5), the quality of blastocyst expansion, internal cell mass (ICM) and trophectoderm was assessed. The number of embryos transferred at D2 or D5 after ICSI depended on their morphology, the age and antecedent of the female partner. Embryo transfer was performed under ultrasound guidance. After transfer, remaining embryos exhibiting good morphology were cryopreserved using a vitrification freezing protocol (Vitrolife, Sweden).

Luteal phase support and pregnancy diagnosis

To optimize embryo implantation, progesterone supplementation was started a few days before embryo transfer or on the evening of the IUI. Progesterone was most commonly administered vaginally (Progestan[®], Besins International, Montrouge, France). It could also be administered orally (Duphaston[®], Theramex, Paris La Défense, France) or subcutaneously (Progiron[®], IBSA Pharma, Antibes, France).

The β -hCG plasmatic level was assessed 14 days after embryo transfer or IUI to diagnose pregnancy. An ongoing clinical pregnancy was defined by visualization of an intrauterine gestational sac with an embryo presenting cardiac activity on ultrasound examination performed at 8 weeks of amenorrhea. After ICSI, the implantation rate (%) was estimated by the number of intrauterine gestational sac per number of transferred embryos.

Statistical analysis

Our primary outcome was the clinical pregnancy rate (CPR, %). Our secondary outcomes were the live birth rate (LBR, %) and the miscarriage rate (%). We only analysed data from ART cycles performed at Rouen University Hospital. The data were collected into a Excel file, and statistical analysis was performed using the IBM SPSS software package. Data are presented as mean \pm standard deviation for continuous quantitative variables and as percentages for qualitative variables. An independent samples t-test was used to compare differences between means, and a Pearson's χ^2 test was used to compare differences in qualitative data, or Fisher's exact test when the sample size was smaller. For survival curves,

the Mantel-Haenszel test was used. A two-tailed P value of less than 0.05 was considered significant.

Ethical approval

The current study is part of the French 'Hors Loi Jardé' non-interventional research programme, and ethical approval was obtained from the Department of Clinical Research and Innovation of Rouen University Hospital (n°1427), based on pre-existing biological and clinical data that were anonymized after collection for further processing. Consequently, no written informed consent was required for data collection and analysis.

Results

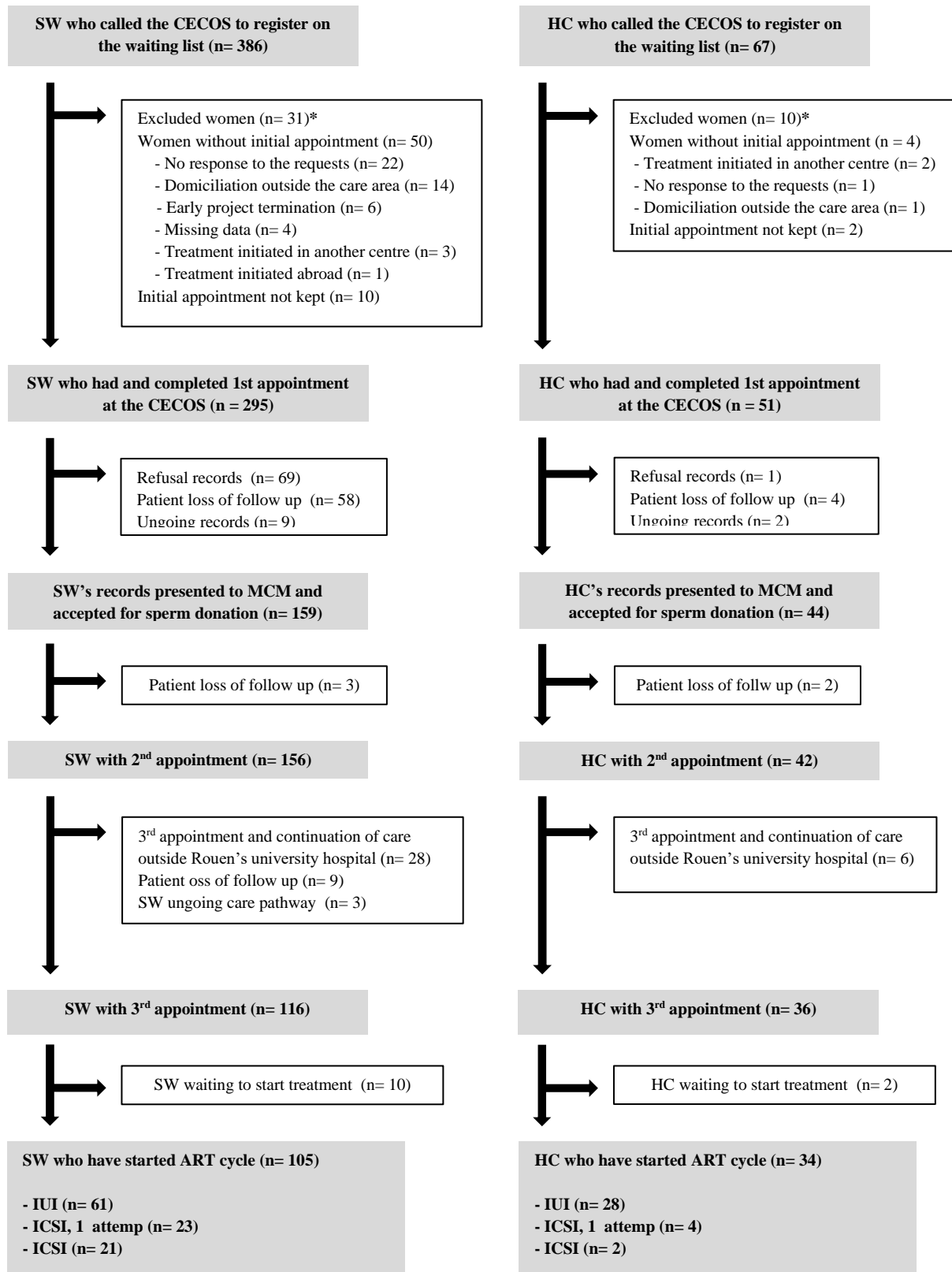
Care pathway data

Between the promulgation of the Bioethics law in August 2021 and 31st December 2022, a total of 386 SW and 68 HC contacted the Reproductive Biology Laboratory-CECOS at Rouen University to request sperm donation; 295 SW and 51 HC initiated the sperm donation care pathway by attending their first appointment, and 105 (36.6%, $n = 105/295$) SW and 34 (50%, $n = 34/68$) HC finally started an ART cycle (**Figure 1**).

There was no significant difference between the two populations in the time necessary to complete the different stages of the sperm donation care pathway. However, **Figure 2** shows that this pathway is long, with an average delay of around 3 months between the date of the first call and the first appointment, and a total of around 15 months between the date of the first call and the start of the first ART cycle. After MCM, the number of refusals is significantly higher for SW compared to HC (29.1%, $n = 69/237$ vs. 2.1%, $n = 1/47$ respectively, $p < 0,001$), representing more than a quarter of the cases (**Table 1**), with the main arguments being impairment of ovarian reserve (78.6%, $n = 55/70$), a medical condition that contre-indicated pregnancy (30%, $n = 21/70$) and woman age (21.4%, $n = 15/70$) (**Figure 3**). In terms of accepted cases, the type of ART chosen was significantly more likely to be IUI for HC (56.0%, $n = 89/159$ in SW vs. 79.5%, $n = 35/44$ in HC, $p = 0,017$) and ICSI procedures for almost half of SW (44.0%, $n = 70/159$ in SW vs. 20.5%, $n = 9/44$ in HC, $p = 0,017$). In addition, the proportion of women who were lost to follow-up after the first appointment is almost twice as high for SW as for HC (23.7%, $n = 70/295$ vs. 11.8%, $n = 6/51$ respectively), even if did not reach the significance ($p = 0.057$). Furthermore, SW were significantly older than WHC at registration and at the time of starting treatment (35.3 ± 4.4 years for SW vs. 31.7 ± 4.9 years for WHC, $p < 0.001$). During the registration period, sperm donation requests were similarly distributed between SW and HC according to the area of residence of the applicants, with the majority coming from Seine Maritime (department 76). The rates of all types of disability and the proportion of women in employment were also similar, although SW significantly more reported having an open-ended contract (45.1%, $n = 115/255$ in SW vs. 0.0%, $n = 0/11$ in WHC, $p = 0.001$).

Figure 1: Flow chart over the inclusion of SW and HC between August 2021 and December 2022.

* : All excluded cases of SW correspond to incomplete patients' electronic medical records, 5 HC were excluded for the same reason, another 5 HC were excluded because they consisted of a cis- gender woman with a trans- gender man.



As mentioned above, in order to balance the number of ART cycles carried out in SW and WHC, 41 HC previously managed in our centre were included in the data collection. Of these 41 additional cases, 35 were accepted for primary IUI cycles and 6 for ICSI cycles. Data from **Table 1** and **Figure 1** only refer to SW and WHC registered at Rouen’s Reproductive Biology Laboratory-CECOS between August 2021 and December 2022.

Figure 2: Frieze showing the average time in days between the different stages of the sperm donation care pathway.

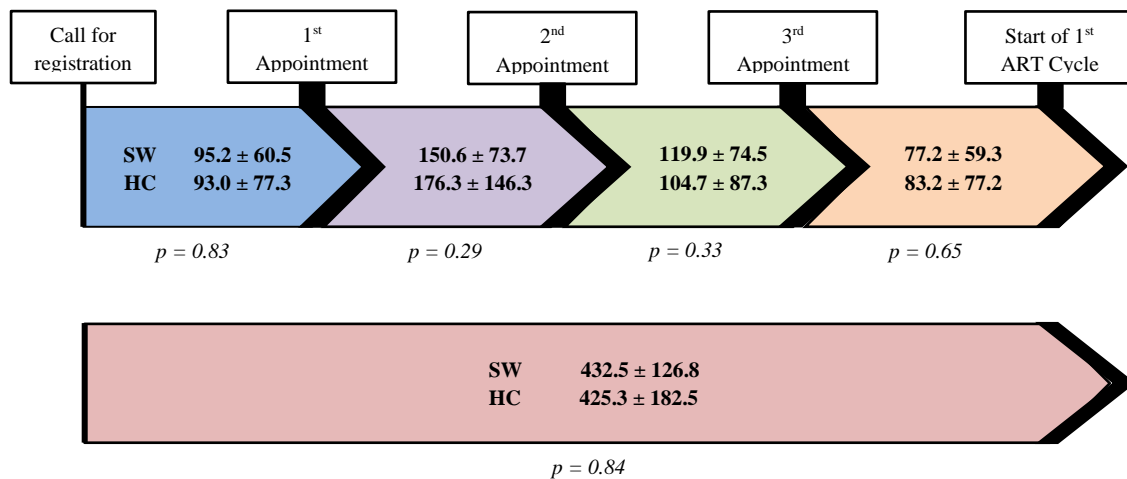


Figure 3: Histograms showing the different reasons for MCM’s refusal

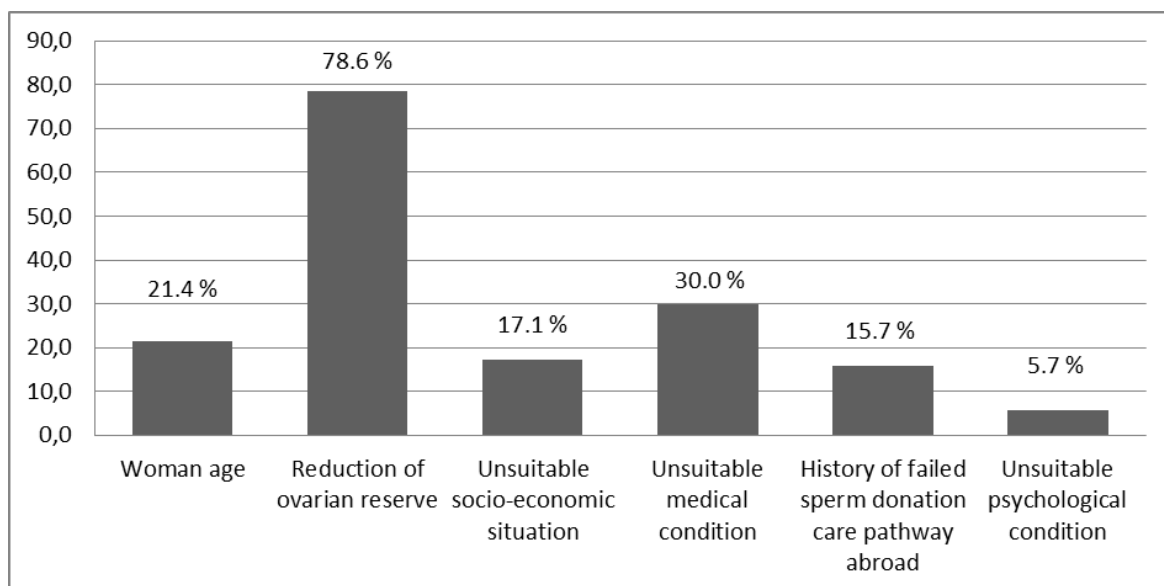


Table 1: Data on care pathway and socio-professional characteristics of SW and WHC who registered between August 2021 and 31st December 2022, and who had a first appointment at the Rouen's Reproductive Biology Laboratory-CECOS.

Parameters	SW, n= 295	HC, n = 51	<i>p value</i>
	Mean ± SD or n (%)		
Age at registration (years)	35.3 ± 4.4	31.7 ± 4.9	< 0.001
Age at start of 1 st ART cycle (years)	35.5 ± 3.4	32.2 ± 4.7	< 0.001
<i>Handicap status</i>	4 (1.4)	2 (3.9)	0.20
Motor disability	3 (75.0)	0 (0.0)	
Sensory-motor disability	1 (25.0)	0 (0.0)	
Mental retardation	0 (0.0)	1 (50.0)	
Other disabilities	0 (0.0)	1 (50.0)	
<i>Professional activity</i>			
Yes	273 (92.5)	39 (88.6)	0.37
Open-ended contract	115 (45.1)	0 (0.0)	0.001
Civil service	84 (32.9)	4 (36.4)	
Unspecified salaried employment	19 (7.5)	4 (36.4)	
Independent/Self-employed	13 (5.1)	1 (9.1)	
Liberal profession	5 (2.0)	1 (9.1)	
Training or professional retraining	3 (1.2)	1 (9.1)	
Fixed-term contract	13 (5.1)	0 (0.0)	
Temporary employment	3 (1.2)	0 (0.0)	
No	22 (7.5)	5 (11.4)	
<i>Department of residence</i>			0.11
76	201 (68.1)	33 (64.7)	
27	81 (27.5)	12 (23.5)	
Outside normandy	10 (3.4)	6 (11.8)	
14	2 (0.7)	0 (0.0)	
61	1 (0.3)	0 (0.0)	
<i>Complete record's status after presentation to the MCM</i>	237 (80.3)	47 (92.2)	< 0.001
Accepted patient record			
Refusal patient record	159 (67.1)	44 (93.6)	
Ungoing patient record	69 (29.1)	1 (2.1)	
	9 (3.8)	2 (4.3)	
<i>First treatment decision for accepted record</i>	159 (53.9)	44 (86.3)	0.005
IUI	89 (56.0)	35 (79.5)	
ICSI	70 (44.0)	9 (20.5)	
Record accepted with continuation of care outside Rouen's university hospital	28 (17.9)	6 (14.3)	0.58
Patients lost to follow-up after first appointment	70 (23.7)	6 (11.8)	0.057

Medical, surgical and gynaecological characteristics

SW and WHC had comparable BMI. There were no differences in smoking or cannabinoid habits between the two groups, but SW consumed significantly less alcohol than WHC (28.2%, $n = 20/71$ vs. 45.5%, $n = 126/277$, $p = 0,008$) (**Table 2**). Medical and surgical history such as appendectomy, hypertension, diabetes, psychiatric, thyroid or neurological disorders were similarly distributed between SW and WHC.

From a gynaecological point of view, although most SW and WHC had regular menstrual cycles, SW were significantly more likely to have amenorrhoea (12.1%, $n = 35/290$ in SW vs. 2.2%, $n = 2/92$ in WHC, $p = 0.005$) associated with the use of continuous taking contraception pill than WHC (15.2%, $n = 43/282$ in SW vs. 1.1%, $n = 1/92$, $p < 0.001$). SW did not report more dysmenorrhoea or even dyspareunia compared to WHC, but pelvic Magnetic Resonance Imaging (MRI) for imaging diagnosis of endometriosis was significantly more common in SW than in WHC (16.8%, $n = 49/292$ vs. 6.7%, $n = 6/90$, respectively, $p = 0.017$). The other major gynaecological pathologies were comparable between the two groups. Only history of tubal pathology was significantly more frequent in SW than in WHC (8.1%, $n = 24/295$ vs. 1.1%, $n = 1/92$, respectively, $p = 0.016$).

The vast majority of SW and WHC were up to date with cervicovaginal screening, but SW had a significantly higher frequency of Human Papilloma Virus (HPV) infection (20.1%, $n = 41/294$ in SW vs. 3.8%, $n = 3/79$ in WHC, $p < 0.001$), associated with cytological abnormalities compared to WHC (19.6%, $n = 41/209$ in SW vs. 3.7%, $n = 3/81$ in WHC, $p < 0.001$), although this did not translate into an increase in conisation in SW ($p = 0.13$). Indeed, the only gynaecological surgery significantly more common in SW than WHC is endouterine curettage (10.6%, $n = 31/295$ vs. 2.2%, $n = 2/92$, respectively, $p = 0.012$).

The age of male partner in HC at enrolment was 35.7 ± 5.3 years. The majority had NOA with failed sperm retrieval after testicular sperm extraction (TESE). In almost a quarter of cases of HC, male infertility remains idiopathic (25.6%, $n = 23/90$), with no known cause. The next most common causes were NOA due to Klinefelter syndrome (16.7%, $n = 15/90$), failure of intraconjugal treatment in men with severe semen parameters alterations (20.0%, $n = 18/90$) and NOA following chemotherapy for malignant disease (11.1%, $n = 10/90$). All data on the male partner of HC can be found in **Table 1** in the Supplementary Appendix.

Table 2: General medical, surgical and gynaecological characteristics of SW and WHC, to be continued... (1)

Parameters	SW, n= 295	WHC, n= 92	p value
	Mean ± SD or n (%)		
<i>General medical data</i>			
Height (m)	1.65 ± 0.07	1.64 ± 0.06	0.11
Weight (kgs)	72.2 ± 17.9	72.8 ± 15.2	0.79
BMI (kgs/m ²)	26.4 ± 6.3	27.0 ± 5.4	0.38
<i>Smoking habits</i>			
Never smoked	188 (65.1)	63 (72.4)	0.41
Smoking cessation	34 (11.8)	7 (8.0)	0.41
Regular smoking	67 (23.2)	17 (19.5)	0.41
Under 10 cig/day	42 (62.7)	7 (41.2)	0.11
10 or more cig/day	25 (37.3)	10 (58.8)	0.11
<i>Alcohol consumption</i>			
None alcohol consumption	126 (45.5)	20 (28.2)	0.008
Occasional alcohol consumption	151 (54.5)	51 (71.8)	0.008
<i>Cannabis consumption</i>			
None cannabis consumption	277 (97.9)	68 (100)	0.60
Occasional or regular cannabis consumption	6 (2.1)	0 (0.0)	0.60
Appendectomy	49 (16.6)	12 (13.0)	0.41
Neurological disorders	40 (13.6)	8 (8.8)	0.23
Thyroid disorders	26 (8.8)	8 (8.7)	0.97
Psychiatric disorders	26 (8.8)	7 (7.7)	0.74
Asthma	18 (6.2)	5 (5.6)	0.83
Bariatric surgery	16 (5.4)	3 (3.3)	0.58
Genetic diseases	10 (3.4)	0 (0.0)	0.13
Autoimmune diseases	8 (2.7)	2 (2.2)	1.00
Arterial Hypertension	8 (2.7)	1 (1.1)	0.69
Cancer	5 (1.7)	1 (1.1)	1.00
Viral hepatitis and HIV seropositivity	4 (1.4)	0 (0.0)	0.58
Diabetes	3 (1.0)	2 (2.2)	0.34
Inflammatory Bowel Disease	3 (1.0)	0 (0.0)	1.00
Medically indicated egg freezing	14 (4.7)	0 (0.0)	0.048
Social egg freezing	1 (0.3)	2 (2.2)	0.14
<i>Gynecological history</i>			
Age of first period (years)	12.6 ± 1.8	11.4 ± 3.6	0.004
<i>Regular menstrual cycles</i>			
Cycles 27-30 days	228 (78.1)	79 (85.9)	0.10
Cycles 27-30 days	164 (73.5)	58 (74.4)	0.004
Cycles 31-35 days	13 (5.8)	13 (16.7)	0.004
Cycles 26 days or less	45 (20.2)	7 (9.0)	0.004
Cycle 36 days or more	1 (0.4)	0 (0.0)	0.004
Amenorrhoea	35 (12.1)	2 (2.2)	0.005
Taking continuous contraception pill	43 (15.2)	1 (1.1)	< 0.001
Virgin women	10 (3.4)	0 (0.0)	0.13
Reported dysmenorrhoea	118 (75.6)	49 (79.0)	0.59
Reported dyspareunia	24 (35.3)	7 (18.9)	0.79

Table 2: General medical, surgical and gynaecological characteristics of SW and WHC... (2)

Parameters	SW, n= 295	WHC, n= 92	<i>p</i> value
	Mean ± SD or n (%)		
<i>Up-to-date cervical cancer screening</i>			
Yes	219 (84.6)	51 (91.1)	0.21
No	40 (15.4)	5 (8.9)	0.21
Pathological cervical cytology	41 (19.6)	3 (3.7)	< 0.001
Cervical HPV infection	41 (20.1)	3 (3.8)	< 0.001
Conization	15 (5.1)	1 (1.1)	0.13
Sexually transmitted infection	28 (12.6)	5 (6.6)	0.15
<i>Tubal pathology</i>			
Unilateral salpingectomy	24 (8.1)	1 (1.1)	0.016
Bilateral salpingectomy	12 (50.0)	0 (0.0)	1.00
Unilateral tubal plasty	6 (25.0)	0 (0.0)	1.00
Bilateral tubal plasty	3 (12.5)	0 (0.0)	1.00
Unilateral sanpinx	3 (12.5)	0 (0.0)	1.00
Bilatéral sanpinx	2 (8.3)	1 (100)	0.12
Bilatéral sanpinx	2 (8.3)	0 (0.0)	1.00
PCOS diagnosis	12 (4.1)	8 (8.7)	0.10
Other ovarian pathology	24 (8.1)	5 (5.4)	0.39
Known adenomyosis	39 (13.2)	7 (7.6)	0.15
Single known fibroid	21 (7.1)	5 (5.4)	0.57
Known polymyomatous uterus	23 (7.8)	2 (2.2)	0.055
<i>Fibroid(s)' impact on the uterine cavity</i>			
Yes	8 (20.5)	1 (16.7)	1.00
No	31 (79.5)	5 (83.3)	1.00
Myomectomy	10 (3.4)	1 (1.1)	0.47
Septal resection	2 (0.7)	0 (0.0)	1.00
Polyp resection	16 (5.4)	3 (3.3)	0.58
Endouterine curettage	31 (10.6)	2 (2.2)	0.012
<i>Endometriosis diagnosed on imaging</i>			
Deep Endometriosis	49 (16.8)	6 (6.7)	0.017
Superficial endometriosis	38 (79.2)	4 (66.7)	0.61
Endometrioma	23 (50.0)	2 (33.3)	0.67
Unilateral	20 (40.0)	2 (33.3)	1.00
Bilateral	11 (57.9)	2 (100)	0.51
Bilateral	8 (42.1)	0 (0.0)	0.51
Endometriosis surgery	20 (38.5)	2 (33.3)	1.00

Fertility history

Although the gravidity is identical in the two populations, the parity was significantly lower in SW compare to WHC (0.10 ± 0.29 vs. 0.37 ± 0.57 , respectively, $p < 0.001$). HC who began sperm donation care pathway, were more frequently parents compare to SW (26.4%, $n = 24/92$, $p < 0.001$), most often through a previous sperm donation in France (91.7%, $n = 22/24$, $p < 0.001$), whereas less than 10% ($n = 28/295$) of SW were mothers most often with children obtained from a previous heterosexual union with natural conception (85.7%, $n = 24/28$) (Table 3). Concerning pregnancy outcomes other than live births, SW reported a significantly higher frequency of recourse to abortion than WHC (19.3%, $n = 57/295$ vs. 3.3%, $n = 3/92$, respectively, $p < 0.001$).

Table 3: Data on previous fertility of SW and WHC

Parameters	SW, n= 295	WHC, n= 92	<i>p</i> value
	Mean ± SD or n (%)		
Time to infertility/time to plan to have a child	3 years	2 years	0.034
Gravidity	0.54 ± 0.95	0.54 ± 1.00	0.99
Parity	0.10 ± 0.29	0.37 ± 0.57	< 0.001
<i>SW or WHC who already have children</i>	28 (9.5)	24 (26.4)	< 0.001
1 child	28 (100)	23 (95.8)	0.46
2 children	0 (0.0)	1 (4.2)	
<i>Child conception method</i>			< 0.001
Natural conception	24 (85.7)	0 (0.0)	
ART with sperm donation in France	0 (0.0)	22 (91.7)	
Intraconjugal ART	0 (0.0)	2 (8.3)	
Artisanal insemination	1 (3.6)	0 (0.0)	
ART with sperm donation abroad	3 (10.7)	0 (0.0)	
Abortion	57 (19.3)	3 (3.3)	< 0.001
Miscarriages	31 (10.5)	6 (6.5)	0.26
Ectopic pregnancy	10 (3.4)	1 (1.1)	0.47
Medical termination of pregnancy	3 (1.0)	1 (1.1)	1.00
Full hydatidiform mole	1 (0.3)	0 (0.0)	1.00

Ovarian reserve and fallopian tube status

Ideally, ovarian reserve assessment should be performed at the beginning of the menstrual cycle and in the absence of hormonal contraception. These sampling conditions were both met significantly less often in SW than in WHC (82.6%, n = 188/228 vs. 98.9%, n = 87/88, respectively, $p < 0.001$) (**Table 4**) because of the higher proportion of SW with secondary amenorrhoea due to continuous contraceptive pills use (15.2%, n = 43/282 in SW, vs. 1.1%, n = 1/92 in WHC, $p < 0.001$) (**Table 2**). However, in women for whom ovarian reserve exploration was performed between day 2 and day 4 of spontaneous menstrual cycles Follicles Stimulating Hormone (FSH) (8.04 ± 5.84 IU/L in SW vs. 6.23 ± 1.93 IU/L in WHC, $p < 0.001$) and 17β oestradiol (51.14 ± 37.30 pg/mL in SW vs. 41.42 ± 20.34 pg/mL in WHC, $p < 0.001$) serum levels were significantly higher in SW than in WHC. Conversely, the ultrasound AFC (13 ± 8 antral follicles in SW, vs. 19 ± 8 antral follicles in WHC, $p < 0.001$) and Anti Mullerian Hormone (AMH) serum level (2.04 ± 2.02 ng/mL in SW, vs. 3.20 ± 1.95 ng/mL in WHC, $p < 0.001$) were significantly lower in SW than in HC. Data of Fallopian tube evaluation and genetic tests such as karyotyping and FMR1 mutation testing did not differ significantly between the two groups.

Table 4: Data on ovarian reserve assessment, fallopian tubes status and any genetic tests of SW and WHC

Parameters	SW, n= 295	WHC, n = 92	<i>p</i> value
	Mean ± SD or n (%)		
Performing ovarian assessment at the start of the menstrual cycle			< 0.001
Yes	188 (82.5)	87 (98.9)	
No	40 (17.5)	1 (1.1)	
Performing ovarian assessment without hormonal contraception			< 0.001
Yes	187 (82.0)	87 (98.9)	
No	41 (18.0)	1 (1.1)	
AMH (ng/mL)	2.04 ± 2.02	3.20 ± 1.95	< 0.001
FSH (IU/L)	8.04 ± 5.84	6.23 ± 1.93	< 0.001
LH (IU/L)	5.15 ± 3.35	4.63 ± 2.05	0.09
17 β Oestradiol (pg/mL)	51.14 ± 37.30	41.42 ± 20.34	0.006
Thyroid-stimulating hormone (TSH, mIU/L)	1.61 ± 0.88	1.63 ± 0.74	0.82
Prolactin (PRL, ng/mL)	16.23 ± 10.44	14.31 ± 5.89	0.053
17 hydroxy progesterone (ng/mL)	0.73 ± 0.44	0.60 ± 0.22	0.050
Testosterone (ng/mL)	0.31 ± 0.17	0.37 ± 0.17	0.057
AFC (follicles number at ultrasound examination)	13 ± 8	19 ± 8	< 0.001
Karyotype	72 (25.8)	32 (36.4)	0.055
Normal (46.XX)	67 (94.4)	32 (100)	
Abnormal (Other than 46;XX)	4 (5.6)	0 (0.0)	
FMR1 mutation or permutation research	56 (20.7)	16 (18.2)	0.61
Presence	0 (0.0)	0 (0.0)	
Absence	100 (100)	100 (100)	
Hysterosalpingography results			0.54
Normal	172 (83.9)	72 (86.7)	
Abnormal	33 (16.1)	11 (13.3)	
AMH ≤ 1.0 ng/mL	99 (36.4)	8 (8.8)	< 0.001

Motivations for seeking sperm donation and donor expectations for SW

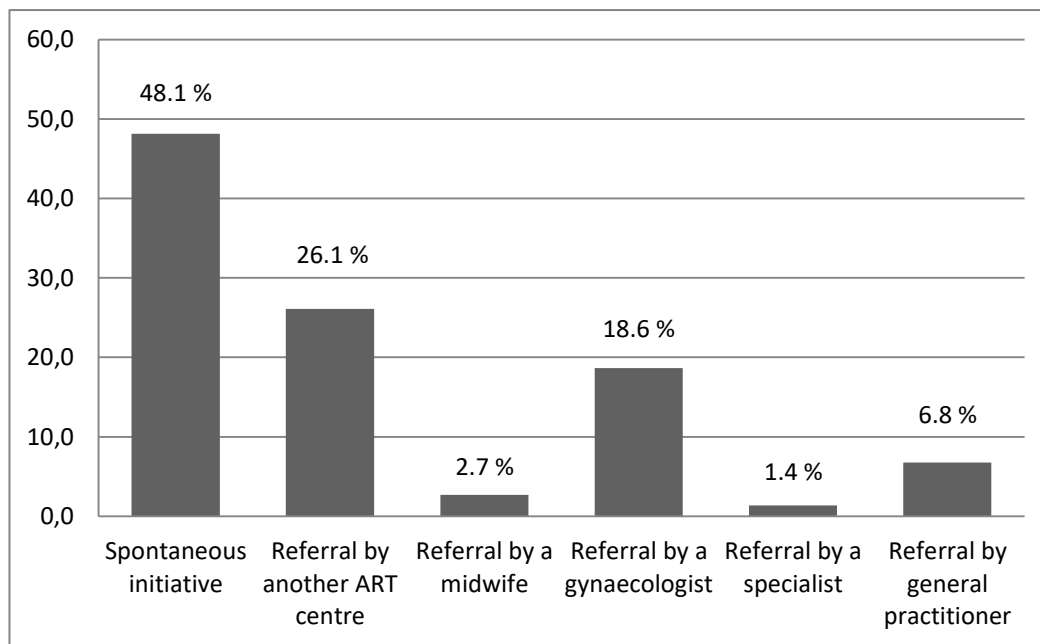
Over 90% of SW reported that they were not in a relationship and lived alone, whether they were tenants or homeowners (45.4%, n = 134/295 vs. 46.4%, n = 137/295, respectively). Of those SW who reported having a partner (5.1%, n = 15/295), often for several years, most of partners were aware of the single mother's project and approved it (Table 5). Most of SW have initiated sperm donation care pathway spontaneously (48.1%, n = 142/295), while others have been referred by another infertility unit (26.1%, n = 77/295) or by their gynaecologist (18.6%, n = 55/295) (Figure 4). In addition, some of them had already started the sperm donation care pathway abroad (9.5%, n = 28/295), either by home insemination or using straws from a foreign donor bank (3.7%, n = 11/295).

Table 5: Data from the questionnaire completed by SW about their lifestyle and their view of sperm donation

Parameters	SW, n = 295 Mean ± SD or n (%)
Way of life	
Living alone	267 (90.5)
Living with a partner	2 (0.7)
Living with parents or family member	18 (6.1)
Living as a tenant or co-owner	7 (2.4)
Missing data	1 (0.3)
Residence type	
Tenant	134 (45.4)
Owner	137 (46.5)
Hosted	18 (6.1)
Missing data	6 (2.0)
Single women in relationship	
With a man	15 (5.1)
With a woman	12 (4.1)
	3 (1.0)
Mean couple duration	2 years
Partner aware of the sperm donation care pathway	11 (3.7)
Partner's opinion on the sperm donation care pathway	
Favourable	4 (36.4)
Rather favourable	4 (36.4)
Not favourable	1 (9.1)
Without opinion	2 (18.2)
ART cycles abroad	
Spain	28 (9.5)
Belgium	18 (6.1)
Other country	9 (3.1)
	1 (0.3)
ART used abroad	
IUI	19 (6.4)
IVF or ICSI	13 (4.4)
Double gamete donation or embryo donation	2 (0.7)
ART cycle in France with a man	9 (3.1)
Homemade insemination or simple stimulation using donor straws	11 (3.7)
Status about access to identifying and non-identifying data	
Favourable or rather favourable	255 (86.4)
Not favourable or rather not favourable	17 (5.8)
Without opinion	19 (6.4)
Missing data	4 (1.4)
Naming the donor for the child	
Person who helped, generous/kind/benevolent person	27 (9.2)
A little seed/gift/"glitter man"	23 (7.8)
Biological/genetic father, donor/genitor	82 (27.8)
Dad/father/parent	4 (1.4)
Don't know, haven't thought about it	94 (31.9)
Missing data	74 (25.1)
Informing the child of his or her mode of conception	
Yes	284 (96.3)
Rather yes	8 (2.7)
Missing data	3 (1.0)
Method of informing the child of the means of conception	
As soon as the child starts asking questions	67 (22.7)
"Age of understanding"	60 (20.4)
As early as possible, fairly/very early, from a very early age/baby	33 (11.2)
From the beginning/as soon as pregnancy/as soon as birth	32 (10.9)
"No precise time, will come naturally, depending on the child"	7 (2.4)
Missing data	96 (32.5)
Matching request	
Matching on own physical characteristics	230 (78.0)
Matching on own blood group	147 (49.8)
Matching on own blood group	11 (3.7)
Matching on own geographical origin	193 (65.4)

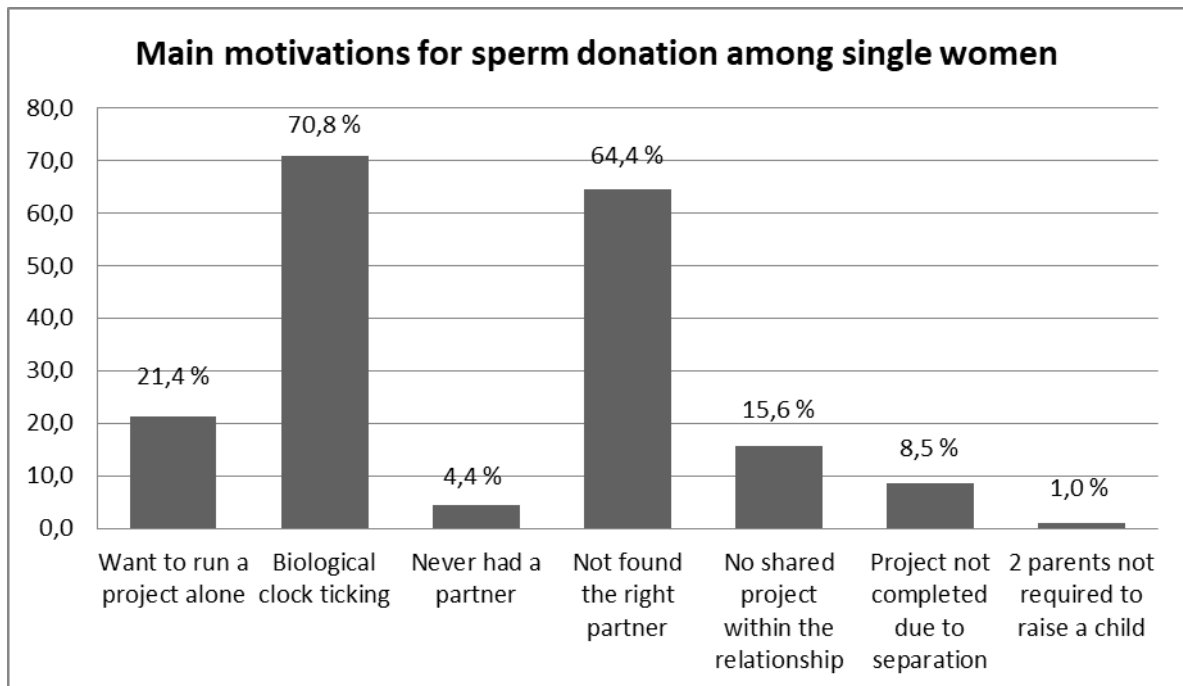
All SW were interviewed at the beginning of their care pathway and, on the whole, they were in favour of informing the child about how he or she was conceived (99.0%, n = 293/295) and of the child having access to the donor's identifying and non-identifying data (86.4%, n = 255/295). Responses were less unanimous regarding the reasons for initiating the sperm donation care pathway, timing of disclosure to the child, representation of the sperm donor or the desire for matching.

Figure 4: Histogram showing how SW are referred to the Reproductive Biology Laboratory-CECOS



Many SW cited the impact of the biological clock (70.8%, n = 209/295), more or less combined with the fact that they had not met a suitable partner (64.4%, n = 190/295), as a reason for initiating sperm donation care pathway, but some of them described a real plan to start a family on their own (21.4%, n = 62/295) (**Figure 5**). More than half of them saw the sperm donor as someone who would help them (52.5%, n = 155/295), and he was also described as altruistic or generous (15.6%, n = 46/295) (**Figure 6**). Naming the sperm donor to the child was more difficult for SW. Over 25% of them (n = 82/295) considered using clear terms such as 'biological father', 'donor' and 'genitor', but many said they had not thought about it (56.9%, n = 168/295) (**Figure 7**).

Figure 5: Main motivations for sperm donation care pathway among SW



There was a lot of missing data on the timing of disclosure to the child, but the answer to this open-ended question generally referred to quite early in childhood, when the child would be able to ask questions. The phrase « old enough to understand » was often used, by almost one in five SW, but it remained highly subjective.

Finally, the truth about the child's mode of conception was essential for SW and so, there was little demand for donor matching to SW's blood group and rhesus (3.7%, n = 11/295). SW preferred to choose a sperm donor whose geographical origin was close to their own (65.4%, n = 193/295) (**Table 5**).

Figure 6: Histogram showing SW's perception of the sperm donor

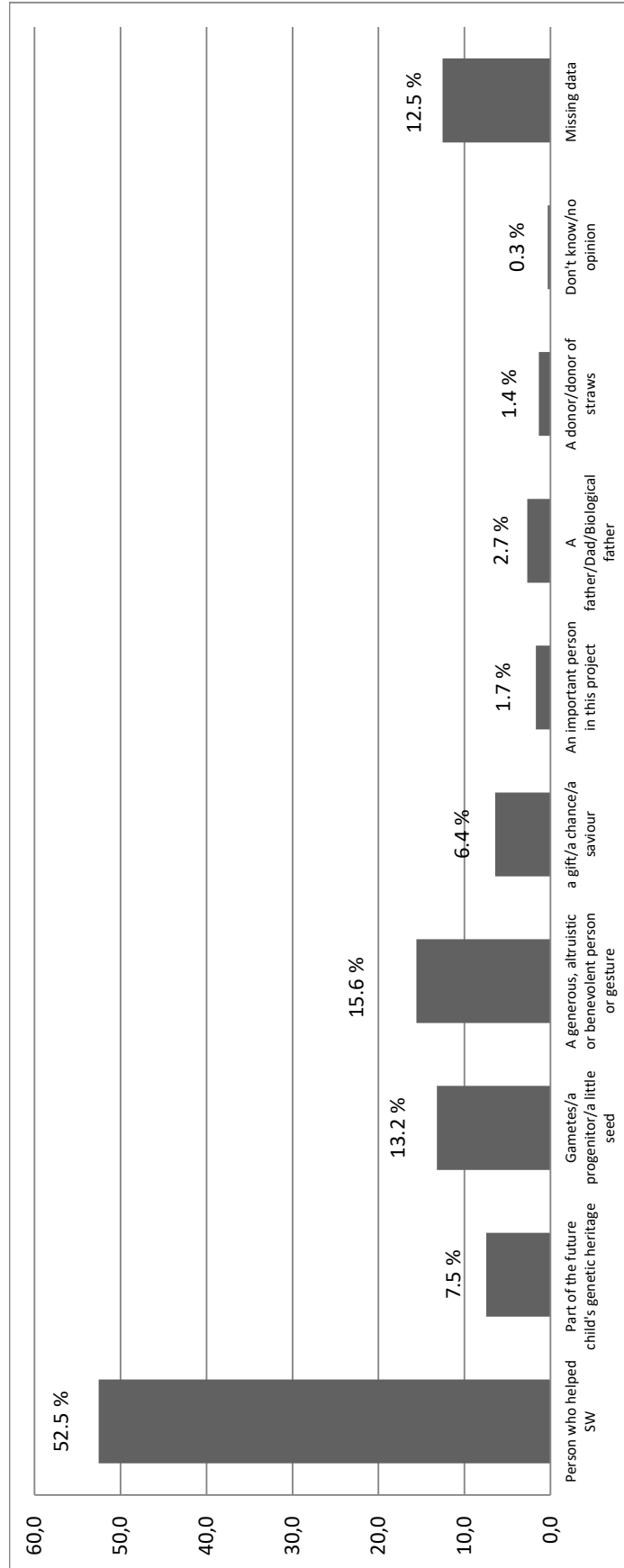
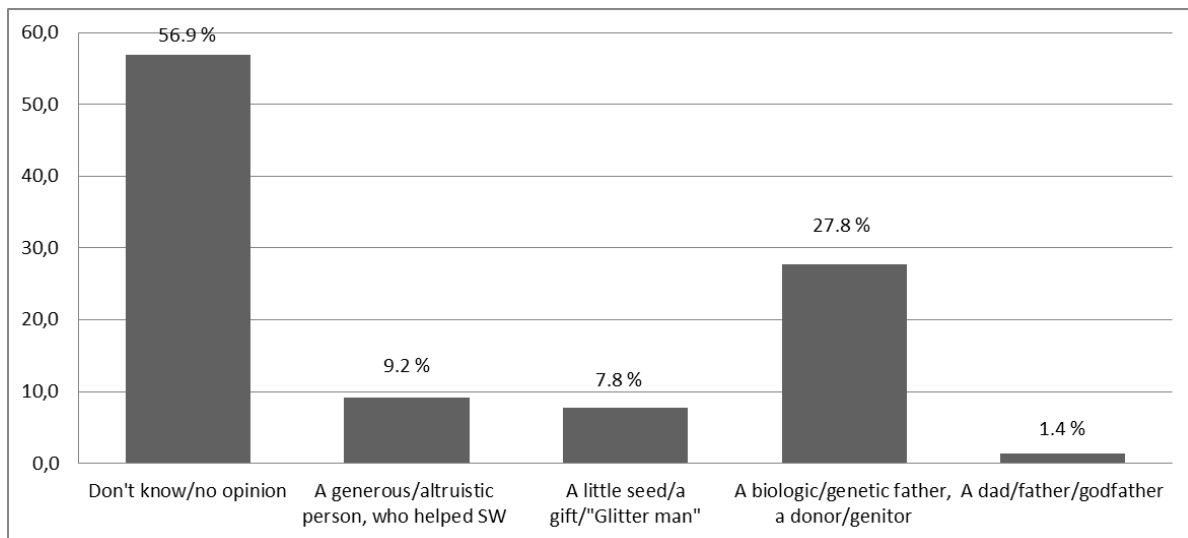


Figure 7: Histogram showing how SW would name their sperm donor to their child



Intrauterine insemination cycles

A total of 312 IUI cycles were performed, 137 in SW and 175 in WHC. There was a significantly difference in the total number of completed IUI cycles ($p = 0.011$), with an average of 2.25 ± 1.4 cycles in SW and 2.85 ± 1.2 in WHC (**Table 6**). The number of SW and WHC who have gone beyond or initiated more than 6 IUI cycles was low. A maximum of 9 IUI cycles were initiated in one WHC, with 5 abandoned IUI cycles. The main cause of abandoned IUI cycles in SW and WHC was premature ovulation (37.1%, $n = 23/62$, vs. 39.7%, $n = 23/58$, respectively). In both groups, there were slightly more drop-outs due to insufficient response to ovarian stimulation (27.4%, $n = 17/62$ in SW, vs. 22.4%, $n = 13/58$ in WHC) than excessive response to ovarian stimulation (24.2%, $n = 15/62$ in SW, vs. 15.5%, $n = 9/58$ in WHC). In addition, WHC had a higher drop-out rate due to personal problems than SW (19.0%, $n = 11/58$, vs. 6.5%, $n = 4/62$, respectively).

The average IUI stimulation duration was approximately twelve days for the two groups. Initial doses of gonadotropins per cycle initiated was higher in WHC than in SW, up to about ten additional daily units for the first four cycles only, but this did not systematically lead to a significant difference in the cumulative dose of FSH per cycle. The use of a GnRH antagonist was significantly more frequent in SW than in WHC (77.4%, $n = 106/137$, vs. 60.4%, $n = 102/169$, respectively, $p = 0.002$). However, the number of ovarian stimulation cycles with a bifollicular response at ultrasound examination was twice as high in the WHC compare to SW (22.3%, $n = 39/175$, vs. 9.1%, $n = 12/132$, respectively, $p = 0.002$).

Table 6: Data on the characteristics and results of IUI cycles, to be continued...(1)

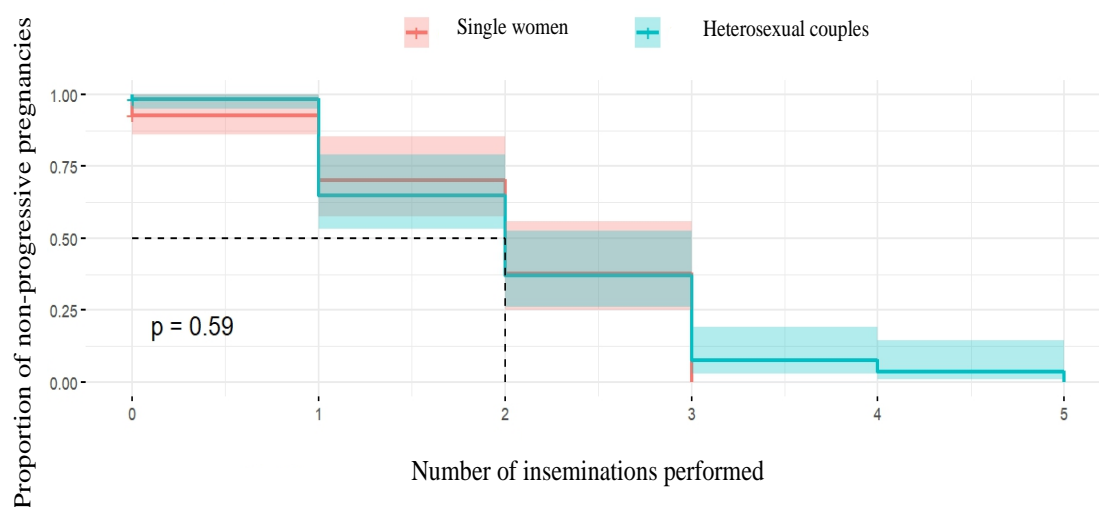
Parameters	SW	HC	<i>p value</i>
	Mean ± SD or n (%)		
Number of IUI initiated cycle	3.26 ± 1.9	3.85 ± 1.8	0.08
Number of complete IUI cycle	2.25 ± 1.4	2.85 ± 1.2	0.011
Number of abandoned IUI cycle	1.1 ± 1.1	1.0 ± 1.2	0.70
<i>Initial gonadotropin dose (IU)</i>			
Cycle 1	41.4 ± 9.3	46.0 ± 12.6	0.023
Cycle 2	40.2 ± 13.8	48.6 ± 15.7	0.005
Cycle 3	40.7 ± 14.0	50.9 ± 16.5	0.005
Cycle 4	45.4 ± 15.9	55.9 ± 18.0	0.021
Cycle 5	48.3 ± 20.0	57.4 ± 21.2	0.23
Cycle 6	51.3 ± 19.0	65.6 ± 25.1	0.15
Cycle 7	54.2 ± 26.0	58.3 ± 21.9	0.81
Cycle 8	75.0	81.3 ± 8.8	0.67
Cycle 9		75.0	
<i>Cumulative FSH dose (IU)</i>			
Cycle 1	471.9 ± 169.9	627.1 ± 311.7	0.008
Cycle 2	499.6 ± 242.1	548.0 ± 297.5	0.45
Cycle 3	412.0 ± 175.0	538.2 ± 268.2	0.050
Cycle 4	529.0 ± 261.5	673.3 ± 340.5	0.12
Cycle 5	612.5 ± 251.1	616.3 ± 427.3	0.98
Cycle 6	602.8 ± 299.5	918.1 ± 664.1	0.21
Cycle 7	600.0 ± 424.3	564.6 ± 227.0	0.88
Cycle 8	1050.0	600.0	
Cycle 9		525.0	
<i>Reason for abandonment</i>			
	62 (31.2)	58 (24.9)	0.15
Premature ovulation	23 (37.1)	23 (39.7)	0.32
Insufficient response	17 (27.4)	13 (22.4)	
Excessive response	15 (24.2)	9 (15.5)	
Personal problem, intercurrent illness	4 (6.5)	11 (19.0)	
Inadequate endometrium	2 (3.2)	1 (1.7)	
Abandonment with no stated reason	1 (1.6)	1 (1.7)	
<i>Introduction of an antagonist</i>			
			0.002
With antagonist	106 (77.4)	102 (60.4)	
Without antagonist	31 (22.6)	67 (39.6)	
<i>Ultrasound follicular status</i>			
			0.002
Monofollicular	120 (90.9)	136 (77.7)	
Bifollicular	12 (9.1)	39 (22.3)	
Mean duration of stimulation (days)	12.6 ± 3.0	12.9 ± 3.4	0.39
<i>Triggering ovulation</i>			
			0.69
Yes	120 (90.9)	154 (89.5)	
No	12 (9.1)	18 (10.5)	
Biochemical pregnancy/total IUI	31 (22.6)	43 (24.6)	0.69
Clinical pregnancy rate/total IUI	27 (19.9)	30 (17.3)	0.57
Ongoing pregnancy at the end of data collection /total IUI	11 (8.1)	3 (1.7)	0.007
Live birth rate /total IUI	14 (10.5)	24 (14.0)	0.37
<i>Number of births/total IUI</i>			
	15	24	0.25
1 (singleton pregnancy)	13 (9.8)	24 (14.0)	
2 (gemellar pregnancy)	1 (0.8)	0 (0.0)	

Table 6: Data on the characteristics and results of IUI cycles... (2)

Parameters	SW	HC	<i>p</i> value
	Mean ± SD or n (%)		
<i>Other pregnancy outcomes /total IUI</i>	6 (4.4)	16 (9.1)	0.10
Miscarriage rate	4 (2.9)	12 (6.9)	
Medical termination of pregnancy	0 (0.0)	1 (0.6)	
Fetal death in utero	0 (0.0)	1 (0.6)	
Ectopic pregnancy	0 (0.0)	1 (0.6)	
Full Hydatidiform mole	0 (0.0)	0 (0.0)	
Missing data on the purpose of pregnancy	2 (1.5)	1 (0.6)	

For all IUI completed cycles, regardless of the rank of cycles, the rate of biochemical pregnancy was similar between SW and HC around 20-25% ($p = 0.69$). Indeed, the CPR and the number of IUI cycles required to achieve half of the all clinical pregnancies remained similar between the two groups (**Figure 8**). Although the LBR did not significantly differ between SW and HC, the percentage of ongoing pregnancies at the end of the data collection period was significantly higher in SW compare to HC (8.1%, $n = 11/135$, vs. 1.7%, $n = 3/173$, respectively, $p = 0.007$). Finally, there was no difference in the total number of other pregnancy outcomes in SW compare to HC.

Figure 8: Kaplan-Meier curve representing the number of IUI required to achieve a clinical pregnancy at the 6 GW ultrasound examination.



Intra cytoplasmic sperm injection and fresh embryo transfer

More than one hundred ICSI cycles have been initiated in our centre; 98 cycles were completed, up to ovarian puncture, 56 cycles for SW and 42 cycles for HC. All these cycles included both SW or HC initially referred for ICSI ($n = 44$ in SW vs. $n = 6$ in HC) and patients who had failed to achieve a live birth after several IUI cycles (14.8%, $n = 9/61$ in SW vs. 17.7 %, $n = 11/62$ in HC). The majority of SW and HC underwent 1 to 2 ICSI cycles and it was mainly in the first cycle that characteristics differ between the two groups. Both the initial dose of gonatropin and the cumulative dose of FSH were higher in SW than in WHC (initial dose, 275.5 ± 71.0 IU, vs. 227.3 ± 68.0 IU, respectively, $p = 0.003$; FSH cumulated dose, 3328.7 ± 1237.3 IU, vs. 2372.3 ± 900.6 IU, respectively, $p < 0.001$) (**Table 7**). More than 80% of ovarian stimulation protocols used were antagonist protocols in SW and WHC. However, SW were significantly more likely to undergo ovarian puncture under local anaesthesia compare to WHC (31.5%, $n = 17/54$, vs. 9.8%, $n = 4/41$, respectively, $p = 0.011$). Taking into account all cycles together, regardless of rank, the average duration of ovarian stimulation was one day longer for SW compare to WHC (12.9 ± 1.5 days, vs. 12.1 ± 1.2 , respectively, $p = 0.011$).

According to the oocyte puncture results, statistical analysis only applies to the first 2 ICSI cycles, as there was insufficient data for cycles 3 and 4. The number of oocytes found was close to the expected number of oocytes estimated during ultrasound monitoring, around ten for SW and WHC. The total number of D2 embryos obtained after puncture, the number of frozen embryos per cycle and the total number of usable embryos per cycle, defined as the sum of the number of embryos used during fresh transfer and those frozen after puncture, remained comparable between SW and WHC, although the fertilization rate was almost 10 points higher in WHC compare to SW during the first ICSI cycle ($78.5 \pm 16.5\%$, vs. $65.9 \pm 24.0\%$, respectively, $p = 0.013$).

Considering all ICSI cycles combined, regardless of the rank, the number of elective single embryo transfer (eSET) and double embryo transfer (DET), and the quality of freshly transferred D2 embryos were comparable between SW and HC. Of the 74 fresh transfers performed, the CPR differed by a factor of two between SW (14.6%, $n = 6/41$) and HC (30.3%, $n = 10/33$), although this did not reach statistical significance ($p = 0.10$). The miscarriage rate was also similar between the SW and HC. However, the LBR was significantly higher in HC compare to SW (24.2%, $n = 8/33$ vs. 4.9%, $n = 2/41$, $p = 0.020$).

Table 7: Data on the characteristics and results of ICSI and fresh embryo transfers cycles, to be continued...(1)

Parameters	SW	HC	<i>p value</i>
	Mean ± SD or n (%)		
Number of ICSI initiated cycle	1.34 ± 0.66	1.47 ± 0.62	0.38
Number of completed ICSI cycle	1.12 ± 0.48	1.31 ± 0.64	0.15
Number of abandoned ICSI cycle	0.22 ± 0.47	0.16 ± 0.45	0.54
<i>Initial gonadotropin dose (IU)</i>			
Cycle 1	275.5 ± 71.0	227.3 ± 68.0	0.003
Cycle 2	266.7 ± 76.6	260.6 ± 72.5	0.84
Cycle 3	225.0 ± 75.0	281.3 ± 79.5	0.48
Cycle 4	300.0		
<i>Cumulative FSH dose (IU)</i>			
Cycle 1	3328.7 ± 1237.3	2372.3 ± 900.6	< 0.001
Cycle 2	3362.5 ± 1516.8	2824.0 ± 921.2	0.32
Cycle 3	2381.3 ± 450.8	3375.0 ± 1431.9	
Cycle 4	3300.0		
<i>Mean duration of stimulation (days)</i>			
Cycle 1	12.9 ± 1.5	12.1 ± 1.2	0.011
Cycle 2	12.8 ± 1.6	12.0 ± 1.3	0.048
Cycle 3	13.1 ± 1.7	12.1 ± 1.1	0.11
Cycle 4	13.0 ± 0.0	13.0 ± 1.4	
Cycle 4	14.0		
<i>Reason for abandonment</i>			
Excessive response	10 (15.6)	5 (10.9)	0.47
Abandonment with no stated reason	2 (20.0)	2 (40.0)	0.64
Insufficient response	3 (30.0)	1 (20.0)	
Inadequate endometrium	3 (30.0)	0 (0.0)	
Premature ovulation	1 (10.0)	2 (40.0)	
Personal problem, intercurrent illness	1 (10.0)	0 (0.0)	
Personal problem, intercurrent illness	0 (0.0)	0 (0.0)	
<i>Type of stimulation protocol</i>			
Antagonist protocol	48 (88.9)	34 (82.9)	0.40
Agonist protocol	6 (11.1)	7 (17.1)	
<i>Type of anaesthesia for oocyte puncture</i>			
General anaesthesia	37 (68.5)	37 (90.2)	0.011
Local anaesthesia	17 (31.5)	4 (9.8)	
<i>Number of oocytes expected</i>			
Cycle 1	9.9 ± 4.8	10.5 ± 4.7	0.60
Cycle 2	10.2 ± 4.5	9.7 ± 4.2	0.78
Cycle 3	10.0 ± 4.2	8.0 ± 0.0	
Cycle 4	19.0		
<i>Number of follicles punctured</i>			
Cycle 1	17.4 ± 15.9	17.8 ± 8.1	0.90
Cycle 2	13.2 ± 6.6	14.8 ± 6.1	0.58
Cycle 3	19.0 ± 12.7	15.5 ± 7.8	
Cycle 4	30.0		
<i>Total number of oocytes found</i>			
Cycle 1	10.3 ± 7.2	11.6 ± 6.1	0.46
Cycle 2	8.4 ± 5.5	8.9 ± 4.4	0.81
Cycle 3	9.0 ± 9.9	7.5 ± 7.8	
Cycle 4	22.0		
<i>Number of mature oocytes injected</i>			
Cycle 1	7.6 ± 6.4	8.4 ± 4.7	0.55
Cycle 2	6.3 ± 3.6	6.9 ± 4.2	0.72
Cycle 3	8.0 ± 9.9	6.0 ± 7.1	
Cycle 4	18.0		

Table 7: Data on the characteristics and results of ICSI and fresh embryo transfers cycles, to be continued... (2)

Parameters	SW	HC	<i>p value</i>
	Mean ± SD or n (%)		
<i>Number of oocytes correctly fertilised</i>			
Cycle 1	5.1 ± 4.9	6.4 ± 3.8	0.23
Cycle 2	4.8 ± 3.0	5.3 ± 2.9	0.73
Cycle 3	6.5 ± 9.2	4.5 ± 5.0	
Cycle 4	15.0		
<i>Fertilization rate (%)</i>			
Cycle 1	65.9 ± 24.0	78.5 ± 16.5	0.013
Cycle 2	78.0 ± 24.1	79.8 ± 17.5	0.85
Cycle 3	43.3 ± 61.3	86.4 ± 19.3	
Cycle 4	83.3		
<i>Total number of embryos obtained at D2</i>			
Cycle 1	7.22 ± 15.6	6.3 ± 3.9	0.77
Cycle 2	4.8 ± 3.0	5.3 ± 2.9	0.73
Cycle 3	6.5 ± 9.2	4.5 ± 5.0	
Cycle 4	15.0		
<i>Total number of top embryos obtained at D2</i>			
Cycle 1	3.8 ± 15.5	2.3 ± 2.3	0.62
Cycle 2	1.8 ± 1.3	1.8 ± 1.4	0.93
Cycle 3	3.5 ± 5.0	2.5 ± 3.5	
Cycle 4	7.0		
<i>Mean number of frozen embryos per cycle</i>			
Cycle 1	2.0 ± 2.8	1.8 ± 2.5	0.70
Cycle 2	1.5 ± 2.1	1.8 ± 2.0	0.78
Cycle 3	4.5 ± 6.4	2.5 ± 3.5	
Cycle 4	8.0		
<i>Total number of usable embryos per cycle</i>			
Cycle 1	3.2 ± 2.4	3.0 ± 2.3	0.81
Cycle 2	2.6 ± 1.6	3.2 ± 1.5	0.40
Cycle 3	5.5 ± 7.8	3.0 ± 2.8	
Cycle 4	8.0		
<i>ICSI cycle without fresh transfer</i>			
Cycle 1	12 (22.2)	9 (22.0)	0.98
Cycle 2	8 (19.5)	6 (22.2)	0.79
Cycle 3	2 (20.0)	2 (16.7)	1.00
Cycle 4	1 (50.0)	1 (50.0)	1.00
Cycle 4	1 (100)		
<i>Reasons for fresh transfer abandonment</i>			
Risk of ovarian hyperstimulation	12 (22.2)	9 (22.0)	0.98
Increased progesterone levels	6 (50.0)	5 (55.6)	
Fertilization failure	2 (16.7)	1 (11.1)	
Inadequate endometrium	2 (16.7)	0 (0.0)	
Embryo culture failure	1 (8.3)	1 (11.1)	
Others causes	1 (8.3)	1 (11.1)	
Others causes	0 (0.0)	1 (11.1)	
<i>Number of embryos transferred</i>			
1 (eSET)	41	33	0.69
2 (DET)	23 (56.1)	17 (51.5)	
2 (DET)	18 (43.9)	16 (48.5)	
<i>Stage of embryonic development (days)</i>			
D2	41	33	0.46
D2	32 (78.0)	28 (84.8)	
D3	9 (22.0)	5 (15.2)	
<i>Quality of embryos transferred at D2</i>			
Top embryo	47	42	0.29
Top embryo	25 (53.2)	27 (64.3)	
No top embryo	22 (46.8)	15 (35.7)	

Table 7: Data on the characteristics and results of ICSI and fresh embryo transfers cycles... (3)

Parameters	SW, n= 41	HC, n=33	<i>p value</i>
	n (%)		
Biochemical pregnancy/total fresh transfer	6 (14.6)	11 (33.3)	0.057
Clinical pregnancy rate/total fresh transfer	6 (14.6)	10 (30.3)	0.10
<i>Implantation rate at ultrasound examination on clinical pregnancy</i>			0.22
50%	5 (12.2)	7 (21.9)	
100%	1 (2.4)	3 (9.4)	
Ongoing pregnancy at the end of data collection/total fresh transfer	2 (4.9)	2 (6.1)	1.00
Live birth rate/total fresh transfer	2 (4.9)	8 (24.2)	0.020
<i>Number of births/total fresh transfer</i>			
1 (singleton pregnancy)	2 (4.9)	8 (24.2)	0.020
<i>Other pregnancy outcomes /total fresh transfer</i>			
Miscarriage rate	2 (4.9)	1 (3.0)	0.087

Frozen embryo transfer

Of the 68 FET performed, only 5 followed a 3rd or 4th ICSI cycles. In the two first ICSI cycles, ~2 FET were performed per patient. Unlike fresh transfers, eSETs were mostly performed in SW and HC (60.6%, n = 20/33 and, 80.0%, n = 28/35, respectively), mainly involving early embryos at day 2; only 2 HC benefited from a single blastocyst transfer at day 5 (**Table 8**). The main reason for FET cycle abandonment in the two groups was, low progesterone levels, below 5 ng/mL after ovulation triggering in stimulated ovarian cycles (47.1%, n = 8/17 in SW, vs. 50.0%, n = 4/8 in HC), whereas this was due to a high risk of OHSS in fresh transfers (50.0%, n = 6/12 in SW, vs. 55.6%, n = 5/9 in HC).

In contrast to the results obtained after fresh transfers, the LBR for FET was comparable between SW and HC ($p = 0.32$). Furthermore, compared to the results obtained with IUI, there was a significant difference in the number of ICSI cycles required to obtain half of the CPR between SW and HC ($p = 0.016$), considering that an ICSI cycle included all embryo transfers performed after ovarian puncture, whether fresh or frozen (**Figure 9**). In WHC, more than 50% of clinical pregnancies were obtained at the 2nd ICSI cycle. Finally, as with the other techniques, the miscarriage rate remained below 7% for all FET performed in both SW and HC ($p = 0.087$).

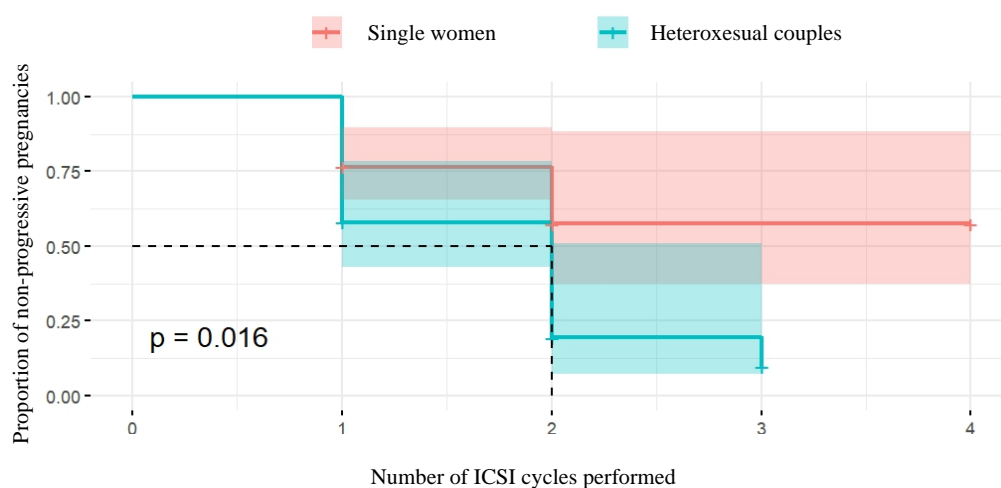
Table 8: Data on the characteristics and results of frozen embryo transfers in SW and HC, to be continued... (1)

Parameters	SW	HC	<i>p value</i>
	Mean ± SD or n (%)		
Number of initiated FET in cycle 1	2.3 ± 1.4	2.1 ± 1.2	0.73
Number of complete FET in cycle 1	1.6 ± 1.0	1.8 ± 1.1	0.67
Number of FET abandoned in cycle 1	0.7 ± 1.0	0.4 ± 0.6	0.29
Number of initiated FET in cycle 2	2.3 ± 1.2	2.2 ± 1.3	0.89
Number of complete FET in cycle 2	1.0 ± 0.0	1.8 ± 1.1	0.18
Number of FET abandoned in cycle 2	1.3 ± 1.2	0.4 ± 0.5	0.16
Number of initiated FET in cycle 3	4.0	2.0	
Number of complete FET in cycle 3	3.0	1.0	
Number of FET abandoned in cycle 3	1.0	1.0	
Number of initiated FET in cycle 4	1.0		
Number of complete FET in cycle 4	1.0		
Number of FET abandoned in cycle 4	0.0		
<i>Protocol type</i>	33	35	0.60
Stimulated cycle	20 (60.6)	19 (54.3)	
Artificial cycle	13 (39.4)	16 (45.7)	
No transfer carried out	17 (34.0)	8 (18.6)	0.095
<i>Reason for abandonment</i>			0.51
Low progesterone after induction	8 (47.1)	4 (50.0)	
Insufficient response	4 (23.5)	1 (12.5)	
Personal problem, intercurrent illness	1 (5.9)	3 (37.5)	
Inadequate endometrium	2 (11.8)	0 (0.0)	
Premature ovulation	1 (5.9)	0 (0.0)	
Ultrasound appearance of salpinx	1 (5.9)	0 (0.0)	
Excessive response	0 (0.0)	0 (0.0)	
<i>Number of embryos transferred</i>			0.08
1 (eSET)	20 (60.6)	28 (80.0)	
2 (DET)	13 (39.4)	7 (20.0)	
<i>Stage of embryonic development (day)</i>			0.62
D2	29 (87.9)	30 (85.7)	
D3	4 (12.1)	3 (8.6)	
D5 (Blastocyst)	0 (0.0)	2 (5.7)	
<i>Quality of embryos at D2</i>			0.28
Top embryo	20 (50.0)	23 (62.2)	
No top embryo	20 (50.0)	14 (37.8)	

Table 8: Data on the characteristics and results of frozen embryo transfers in SW and HC...(2)

Parameters	SW	HC	p value
	Mean ± SD or n (%)		
Biochemical pregnancy/total FET	9 (27.3)	12 (35.3)	0.48
Clinical pregnancy rate/total FET	9 (27.3)	10 (30.3)	0.79
<i>Implantation rate at ultrasound examination for progressive pregnancy</i>			0.92
50%	3 (9.1)	2 (6.5)	
100%	6 (18.2)	7 (22.6)	
Ongoing pregnancy at the end of data collection/total FET	3 (9.1)	3 (9.1)	1.00
Live birth rate /total FET	4 (12.1)	7 (21.2)	0.32
<i>Number of births /total FET</i>	5	7	0.30
1 (singleton pregnancy)	3 (9.1)	7 (21.2)	
2 (gemellar pregnancy)	1 (3.0)	0 (0.0)	
<i>Other pregnancy outcomes/total FET</i>	2 (6.0)	3 (8.6)	0.75
Miscarriage rate	1 (3.0)	1 (2.9)	
Missing data on the purpose of pregnancy	1 (3.0)	2 (5.7)	

Figure 9: Kaplan-Meier curve showing the number of ICSI cycle required (including fresh and FET) before obtaining a clinical pregnancy at the 6 GW ultrasound examination.



Discussion

In the current study, we have performed a first overview of sperm donation care pathway among SW since the changes in the French Biotethics law in 2021. To the best of our knowledge, this is the first French that explored gynealogical and reproductive health of SW, examines their motivations concerning their parental project using sperm donation, the representation they had of sperm donors and the representation they would pass on to their future child. This study also examined ART (IUI or ICSI) cycle outcome performed at the Rouen University Hospital, in comparison to a population of HC.

Although this new access to single motherhood using gamete or embryo donation is now available throughout France, third party MAR is a lengthy care pathway requiring clinical, biological and radiological examinations, often repeated, as well as a certain psychological commitment and rigorous administrative organisation for women undergoing it. On 30th June 2023, the French Agency of Biomedicine described a national waiting time from the first appointment to the first ART cycle in the first half of 2023 of 15.8 months, which is comparable to that of our centre reported in this current study, but which has increased at a national level by more than a month compared to the second half of 2022. Indeed, although the acces of initial medical consultations for third party MAR has gradually increased throughout France, the number of requests has also continued to increase of close to 25% between the second semester of 2022 and the first semester of 2023. The evolution of these requests during our registration period at the Reproductive Biology Laboratory-CECOS showed two peaks of incidence for SW, with a maximum of requests recorded after the promulgation of the law in October 2021 (48 requests), then to a lesser extent in July 2022 (29 requests), followed by a period of stabilisation during the rest of the second semester of 2022, with a number of requests varying from 15 to 20 calls per month. (**Figure 1** in supplementary appendix). However, in comparison to the 2023's March report, there has been a reduction in the number of people on the waiting list for sperm donation care pathway, and the distribution is less egalitarian than before, with almost 20% of HC on the waiting list compared to 40% of SW and LC (1^{ère} réunion du comité national de suivi du Plan PEGh, Agence de la biomédecine, 2023). This long delay in care pathway could explain the number of lost to follow-up, which, although not significant in our study ($p = 0.057$), was twice as high for SW as for WHC (23.7%, $n = 70/295$ vs. 11.8%, $n = 6/51$, respectively). The different reasons for loss to follow-up can be seen in **Table 2** in the supplementary appendix.

One of the main well-established predictors of female fertility is maternal age at conception, significantly higher in our SW at enrolment and at the start of the first ART cycles compare to WHC (**Table 1**). This finding has been frequently reported in SW when considering CPR not only in comparison to HC or LC requiring sperm donation but also HC performing autologous IUI (Soares et al., 2019 ; Wrande et al., 2022). In France, the average age at first birth has risen steadily since 1974, from 24.0 years to almost 28.5 years in 2015 (INSEE premiere N°1642, 2017). In its latest demographic report for 2023, the French National Institute for Statistics and Economic Studies (INSEE) even shows that the average age at first birth has exceeded 30 years since 2022 and is now stable at around 31 years (INSEE première N° 1978, 2024). Since 1980, this gradual delay at first birth has been accompanied by an increase in the fertility among women over 40, with almost 5.7% of births in France being "late" in 2019 (INSEE première N°1885, 2022). However, due to a significant decline in natural fertility combined with an increase of spontaneous miscarriages, the age of over 35 years has been identified as the threshold age beyond which we can consider advanced maternal age (Heffner, 2004). The reasons for and consequences of the increasing age at first pregnancy in Europe have been the subject of numerous studies. In a review published over ten years ago, the ESHRE explained that this massive postponement of motherhood was the result of a mismatch between the period when women are building sustainable careers and their biologically optimal time to conceive. The rise of the pill since the 1960s, increased levels of education and labour market participation, coupled with the promotion of social values such as gender equality and the desire for some economic stability and adequate housing before starting a family, have all contributed to this major phenomenon in France and abroad (Mills et al., 2011). In our study, although there are a number of missing data on the professional activities of WHC, none of them reported open-ended contract, in contrast to almost half of SW (45,1%, n =115/255, vs. 0.0%, n = 0/11, respectively, $p = 0.001$) (**Table 1**). This motherhood posponement has had a number of demographic and medical consequences, especially regarding natural fertility, with women reducing the ideal number of children initially planned and experiencing more frequent obstetric adverse events such as spontaneous miscarriage, ectopic pregnancy and fetal death *in utero* (Schmidt et al., 2012). Moreover, the development of ART and the laws permitting the use of donor gametes are often seen by these women, particularly those who value professional success when planning their pregnancy, as an issue of having a good chance of obtained a child even when they are approaching 40. (Simoni et al., 2017). These recent data highlight the fact that there is still a misconception in our societies about not only women's natural fertility and how it decreases, particularly at

advanced maternal age, but also about access and opportunities offered by MAR (Mac Dougall et al., 2013).

Considering that each woman has a defined stock of oocytes at birth, that constantly decreases until the onset of the menopause, mainly due to apoptosis mechanisms, there is no physiological recovery during a woman's reproductive life, since oogenesis is a phenomenon that only occurs during embryonic life (Baker T.G., 1963; De Pol et al., 1997). This continuous quantitative loss of oocytes is accompanied by a change in oocyte quality with maternal age, which results in an increase in the incidence of numerical chromosomal anomalies due to meiotic non-disjunction phenomena, leading to an increase in the number of aneuploid embryos (Mikwar et al., 2020 ; Cimadomo et al., 2018) responsible for repeated miscarriages, or an increasing number of foetal trisomies, such as Down syndrome, more frequently diagnosed after maternal age of more than 35 years (Morris et al., 2002). In IVF or ICSI, the quality of the oocytes and embryos can be described by studying morphological and morphokinetic parameters. However, there is no simple routine test to assess oocyte or embryo quality, unlike the quantitative exploration of ovarian reserve. AFC, FSH and LH serum levels, estradiol and AMH produced by antral follicles measured at the beginning of the menstrual cycle provide an estimate of ovarian reserve and potential response to ovarian protocols stimulation (Iwase et al., 2018). Our SW who were older than WHC, had a significant lower ovarian reserve, with higher FSH and estradiol serum levels, associated with lower AFC and AMH serum level (**Table 4**). Moreover, considering the AMH cut-off of around 1 ng/mL to define women with low ovarian reserve according to 2011 Bologna criteria developed by ESHRE (Younis et al., 2015), more than a third of our SW had an MAH level below this cut-off value (36.4%, $n = 99/272$), compare to only 8.8% of WHC ($n = 8/91$, $p < 0.001$) (**Table 4**). However, these results must be treated with caution, as hormone measurement must be performed at the beginning of the menstrual cycle and without using hormonal contraception in order to be interpretable. Indeed, we also showed that the use of hormonal contraception was significantly less fulfilled in SW than in WHC. In addition, the inter-laboratory variability of AMH measurement and the inter-operator variability of AFC in pelvic ultrasound examination contribute to a less accurate estimate of ovarian reserve, as results such as « not dosable AMH », « AMH > 9.0 ng/ml », « AFC > 40 fols » were excluded from statistical analysis. Clinically, this reduction in ovarian reserve may also be suspected in case of shortening menstrual cycles. Although there was no difference in the number of

women with regular cycles in our study, SW were significantly more likely to have short cycles of 26 days or less than WHC (20.2%, $n = 45/223$, vs. 9.0%, $n = 7/78$, respectively, $p = 0.004$) (**Table 2**).

To curb this phenomenon of postponing motherhood, health and social policies must better inform women about the normal evolution of their natural fertility. A French study of 285 young midwifery students at the end of their medical studies showed that only 22% thought that fertility declined after the age of 35, and more than 85% thought that IVF allowed a woman to become pregnant even if her ovarian reserve was significantly reduced. In addition, if these young women were faced with a personal situation of ovarian insufficiency, almost three quarters of them would agree to bring forward their parental project and more than half of them would be willing to undergo social egg freezing (Chelli et al., 2015). However, social egg freezing, also permitted since 2021 by the French bioethics law, offers additional possibility of becoming pregnant at an older age, as long as there is a sufficient number of cryopreserved oocytes, which is not always reached for all women (Coello et al., 2018 ; Goldman et al., 2017).

In addition to oocyte quantity and quality, other factors associated with natural fertility may change with maternal age. This is particularly true for endometrium quality and receptivity, which are essential for embryo implantation. (Ntostis et al., 2021 ; Pathare et al., 2023). These parameters can also be damaged during a woman's lifetime by repeated endometrial surgery, such as endouterine curettage, which can cause intrauterine synechiae, even Asherman's syndrome, during surgical abortion or in the context of trophoblastic retention after miscarriage (Dinh et al., 2024). In our study, the mean gravidity was similar in SW and WHC. However, parity, defined as the number of deliveries after the viability period of 22 weeks of amenorrhoea by world health organization, was significantly lower in the SW, who were also more likely to have had a prior abortion ($p < 0.001$), probably often surgical, given the concomitant difference in the number of patients who had already had a endouterine curettage ($p = 0.012$) (**Table 2 & 3**). While the natural fertility of SW might initially appear comparable to that of WHC, as they had a similar gravidity at enrolment, specific gynaecological history, such as endometriosis, known to cause infertility were more common among our SW (**Table 2**) and can have a negative impact on their chance of delivery after third party ART (Macer & Taylor, 2012). The reported percentage of our SW with endometriosis may partly explain the higher proportion of SW taking continuous contraceptive pills to limit disabling symptoms

such as dysmenorrhoea and dyspareunia, which were difficult to assess in our study due to missing data (**Table 2**). In addition, the fact that SW continued to be sexually active while starting sperm donation care pathway justifies an effective contraception, usually continuous progestive contraception, to limit cardiovascular risk in our SW, whose average age at registration was 35 years.

From a gynaecological point of view, although studies showed a lack of gynaecological follow-up, especially with regard to cervicovaginal screening among lesbian women (Agénor et al., 2014), the majority of our SW were up to date with their gynaecological follow-up, and SW were probably even seen more regularly by their practitioners, as they were more likely to be HPV carriers and to have cervix anathomopathological lesions, requiring more regular follow-up. As HPV transmission is almost exclusively sexual, it seems legitimate that our SWs were more likely to be infected in the absence of a stable sexual partner (Burchell et al, 2006). A recent German study over 2,500 women aged between 30 and 65 years, found a prevalence of HPV infection of 13.8% in SW and 13.6% in women aged between 30 and 39 years, which is lower than the prevalence found in our SW (20.1%, n = 41/204) (Liang et al., 2024). However, there was no significant difference in the prevalence of other sexually transmitted infections in SW compared to WHC.

Prior to France, other European countries that have allowed third party MAR for SW, have also examined the reasons that lead SW to make this choice of motherhood using sperm donation. Indeed before bioethics law changes, French SW wishing to undergo sperm donation chose to initiate their MAR process abroad, facing numerous organisational, cultural and financial challenges (Van Hoof et al., 2015). Combined with their own fears and stigmatisation, SW are exposed to the judgment of their surrounding society (Graham, 2018 ; Volgsten & Schmidt, 2023), and to the inadequate training of the health professionals, they or their future children will encounter (Armuan et al., 2020). Indeed, only a few SW in our current study mentioned a real plan for single motherhood as their main motivation. Most of them referred to the idea of the 'biological clock' associated with an absence of a stable relationship or a partner suitable for building their family project, as Swedish women had mentioned a few years earlier in the study of Volgsten & Schmidt (2021). Even now accessible in their home country, motherhood with third party MAR is not an obvious choice for our French SW. Although almost all of our SW agreed on the importance of informing

their future child about how he or she was conceived, their perception of the most appropriate moment to transmit this information remained more uncertain. In the open-ended questionnaire, the frequently used expression « old enough to understand » was very often associated with early childhood, when the child starts to talk and ask questions, but sometimes further back in the child's psychological development that means in the teenage years. Some SW who used this expression also specified the age to which they were referring (**Figure 2** in supplementary appendix).

In our study many ART cycles had to be abandoned, especially IUI cycles. The main reason for abandonment in SW and WHC was premature ovulation (**Table 6**), which may be explained by the fact that IUI were not performed during weekends in our centre. In addition, although not significant, more IUI cycles were cancelled due to personal problems in HC. As the presence of the spouse was required for IUI in our center, it is possible that this could lead to involuntary cancellation of procedures, especially due to work constraints. Of all attempts initiated in the SW and HC included, almost 92 reached our primary outcome. Irrespective of the technique used, IUI, fresh or frozen embryo transfer, there was no significant difference between SW and HC in CPR, without adjustment for age and considering each cycle independently for each women, contrary to data reported in other countries ((De Brucker et al., 2009, 2013, 2014 ; Catalini et al., 2023). Almost 59 live births were recorded, 20 in our SW and 39 in our HC at the end of the data collection period. Only live births rate after fresh embryo transfer were significantly different, with almost a quarter of fresh embryo transfers in HC resulting in a live birth, compared to only 5% in SW ($p = 0.020$). While the other abnormal obstetrical events reported during pregnancy in our study were rare and mainly related to the vitality of the foetus *in utero*, such as miscarriage rate of less than 7% considering all ART cycles (**Table 6, 7 & 8**), a large number of studies have looked at the main maternal obstetrical complications and birth outcomes of children born after donor sperm donation. The risk of hypertensive disorders of pregnancy and pre-eclampsia seems to be higher after IUI with donor sperm than after IUI with partner sperm. However, the rate of preterm delivery does not seem to be affected by the use of donor sperm, and the risk of low birthweight to be reduced after IVF with sperm donation (Pohjonen et al., 2022 ; González-Comadran et al., 2014).

In addition to the ART cycles performed with sperm donation during our study, almost 43 SW of the 69 refused at the MCM were referred to a double gamete donation or embryo donation

pathway. Out of the 51 HC that were registered between August 2021 and December 2022, only 1 was refused and no further treatment was offered (**Table 3** in supplementary appendix).

A total of 10 double gamete donation cycles and 8 embryo donation cycles were performed in our SW during the data collection period. All of these cycles were artificial, with a median treatment period of approximately 20 days prior embryo transfer. The CPR was 30-40% for both technique in the 2 groups.. For secondary outcomes, the LBR rate was 10-20% and the miscarriage rate was 20-30% for SW and WHC in the both techniques (**Table 4** in supplementary appendix). The low number of cycles performed be explained by the fact that in the case of double gamete donation cycles using fresh oocytes, there is an additional delay in pathway because the number of oocyte donors, who were not remunerated in France, is lower than the demand. The absence of cycle for double gamete donation or embryo for HC did not allow a comparative analysis between the 2 groups.

Although our study is the first one in France to examine such a large sample of this new population of SW, our study has some limitations and overall data might vary over time for several reasons. Firstly, our study is based on retrospective data with missing data mostly in HC and included potentially a limited number of patient. Secondly, many pregnancies were still occurring at the end of data collection, more in SW than in HC, especially those obtained following IUI. Thirdly, the statistical analyses were independent of the number of treatment cycles per patient and per technique, whereas some patients achieved pregnancy after fresh embryo transfer or FET after several failed IUI attempts, making their treatment longer and therefore their age at conception higher. Finally, the results of our study may not be fully extrapolable to the national level or superimposable in the longer term, considering its monocentric nature, focusing on SW and HC recorded in the first 18 months after the French Bioethics law changes were passed.

Conclusion

Our study is the first to provide initial feedback on sperm donation in SW in France. As reported in the literature, these women were older throughout the treatment and had a reduced ovarian reserve, but regardless of the adjustment for age and number of treatment cycles performed, there was no significant difference between these first ART attempts in terms of CPR and miscarriage rate, compared with the reference population of HC. Only the live birth rate after fresh embryo transfer was significantly better in HC than in SW. Further studies are therefore needed to confirm our data, to assess their reproducibility, and it may be interesting to compare them with those obtained in women of lesbian couples accessing sperm donation in France after the bioethical revision.

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Supplementary Appendix

Table 1: Baseline characteristics of men in HC, to be continued... (1)

Parameters	Men in HC, n= 98 Mean \pm SD or n (%)
Age at registration (years)	35.7 \pm 5.3
Age at start of 1st treatment (years)	36.2 \pm 5.3
<i>Handicap status</i>	4 (4.3)
Motor disability	2 (50.0)
Sensory-motor disability	1 (25.0)
Missing data	1 (25.0)
<i>Professional activity</i>	81 (86.2)
Yes	6 (6.4)
No	7 (7.4)
Missing data	
Heterosexual Couples lifetime	7 years
Previous intraconjugal treatment	30 (32.6)
<i>Causes of male infertility</i>	
Idiopathic causes	23 (25.6)
Sperm alterations and intraconjugal management failure	18 (20.0)
Klinefelter's syndrome	15 (16.7)
Tumour-related causes/post-chemotherapy azoospermia	10 (11.1)
AZF microdeletion	9 (10.0)
Other genetic causes	7 (7.8)
Sertoli cell-only syndrome	7 (7.8)
Bilateral testicular agenesis	1 (1,1)
<i>General medical data</i>	
Height (m)	1.80 \pm 0.1
Weight (kgs)	87.9 \pm 22.7
BMI (kgs/m ²)	27.4 \pm 6.7
<i>Smoking habits</i>	
Never smoked	33 (37.5)
Smoking cessation	22 (25.0)
Regular smoking	33 (37.5)
Under 10 cig/day	13 (40.6)
10 or more cig/day	19 (59.4)
<i>Alcohol consumption</i>	
None alcohol consumption	14 (18.4)
Occasionnal alcohol consumption	61 (80.3)
Regular alcohol consumption	1 (1.3)
<i>Cannabis consumption</i>	
None cannabis consumption	63 (86.3)
Cannabis cessation	3 (4.1)
Regular or regular consumption	7 (9.6)

Table 1: Baseline characteristics of men in HC, to be continued... (2)

Parameters	Men in HC, n= 98 Mean ± SD or n (%)
<i>Urological history</i>	
Testicular torsion	1 (1.1)
<i>Type of testicular torsion</i>	
Unilateral	1 (100)
Bilateral	0 (0.0)
Orchiectomy following testicular torsion	0 (0.0)
Urogenital infection	4 (4.7)
Cryptorchidism	22 (24.2)
<i>Type of cryptorchidism</i>	
Unilateral	13 (59.1)
Bilateral	9 (40.9)
Cryptorchidism surgery	17 (89.5)
Testicular trauma	9 (12.2)
Varicocele	4 (4.4)
<i>Type of varicocele</i>	
Unilateral	3 (75.0)
Missing data	1 (25.0)
Embolisation of varicocele	1 (25.0)
Erectile dysfunction	5 (11.1)
Mumps in childhood	6 (14.6)
Cancer	10 (10.9)
<i>Type of cancer</i>	
Hodgkin's lymphoma	4 (40.0)
Testicular cancer	3 (30.0)
Leukaemia in childhood	1 (10.0)
Cerebral glioma	1 (10.0)
Neuroblastoma	1 (10.0)
<i>Chemotherapy</i>	
Yes	8 (80.0)
Missing data	2 (20.0)
<i>Radiotherapy</i>	
Yes	0 (0.0)
No	3 (30.0)
Missing data	7 (70.0)

Table 1: Baseline characteristics of men in HC...(3)

Parameters	Men in HC, n= 98 Mean \pm SD or n (%)
Hormonal assessment	80 (92.0 %)
FSH (IU/L)	22.0 \pm 14.4
LH (IU/L)	11.1 \pm 9.0
17 β Eostradiol (pg/mL)	30.6 \pm 12.9
Testost�rone (ng/mL)	4.1 \pm 2.1
Inhibin B (pg/mL)	46.5 \pm 48.8
Sex Hormone-Binding Globulin (nmol/L)	36.8 \pm 25.8
Genito-urinary ultrasound	71 (91.0)
Ultrasound testicular atrophy/hypotrophy	47 (74.6)
Ultrasound varicocele	12 (17.9)
<i>Type of ultrasound varicocele</i>	12
Unilateral	8 (66.7)
Bilateral	4 (33.3)
Sperm and genetic analysis	
<i>Spermogram results</i>	85
Azoospermia	72 (84.7)
Oligo-astheno-teratozoospermia	9 (10.6)
Normal spermogram	4 (4.7)
Testicular biopsy	65 (76.5)
<i>Testicular biopsy results</i>	65
Negative	50 (76.9)
Positive	11 (16.9)
Rare spermatozoa	4 (6.2)
Karyotype	89
46 (XY)	67 (75.3)
47 (XXY)	16 (18.0)
Y chromosome isodicentricity	1 (1.1)
Monosomy X mosaic associated with Y chromosome isodicentricity	1 (1.1)
Autosomal reciprocal translocation	2 (2.2)
Translocation involving the Y chromosome	2 (2.2)
Y chromosome microdeletion	9 (16.1)
<i>Type of Y chromosome microdeletion</i>	9
AZF a	0 (0.0)
AZF b	1 (11.1)
AZF c	4 (44.4)
AZF b + c	3 (33.3)
AZF a + b + c	1 (11.1)

Table 2: Reasons of lost of follow-up in SW and HC registered between August 2021 and December 2022

Parameters	SW, n = 295	HC, n = 51	p value
	n (%)		
<i>Reasons of lost of follow-up</i>	70 (23.2)	6 (11.8)	0.057
No more news	26 (37.1)	2 (33.3)	
Stopping care pathway for personal reasons	25 (35.7)	1 (16.7)	
Stopping care pathway because ongoing pregnancy	8 (11.4)	1 (16.7)	
Stopping pathway because starting a relationship	7 (10.0)	0 (0.0)	
Starting pathway in another French ART center	2 (2.9)	0 (0.0)	
Stopping pathway because starting pathway abroad	2 (2.9)	0 (0.0)	
Stopping pathway because separation of the HC	0 (0.0)	2 (33.3)	

Figure 1: Number of calls per month made to the CECOS of the Rouen University Hospital by single women requesting a first appointment

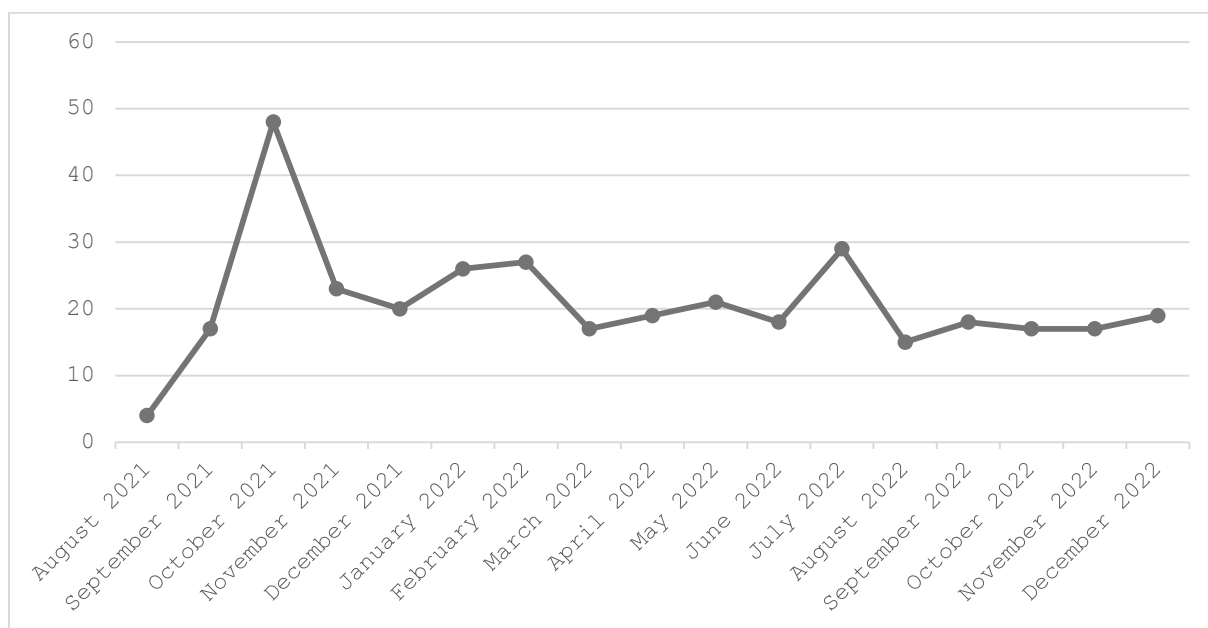


Figure 2: Histograms showing what's "old enough to understand" for several SW

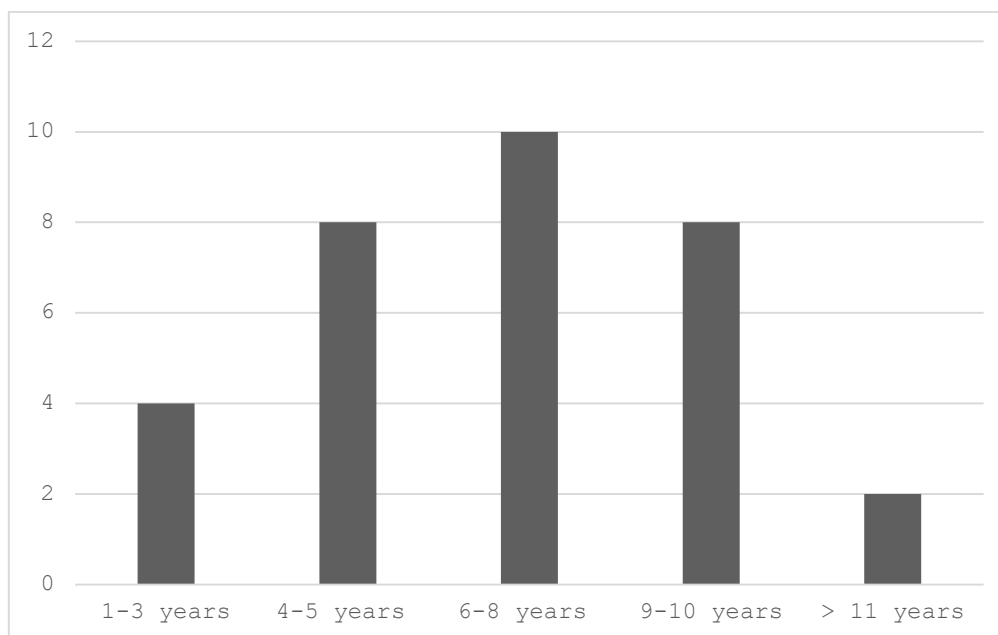


Table 3: Referral decision for SW and HC refused at MCM for sperm donation

Parameters	SW, n = 295	HC, n = 51	p value
	n (%)		
Refusal records after MCM	69 (29.1 %)	1 (2.1 %)	< 0.001
Accepted records for double gamete donation or embryo donation	43 (62.3 %)	0 (0.0 %)	0.39

Table 4: Data on the characteristics and results of double gamete donation cycles and embryo donation cycles in SW

Parameters	SW	
	Mean \pm SD or n (%)	
	Double gamete donation	Embryo donation
Cycle initiated	1.2 \pm 0.3	1.4 \pm 0.5
Complete Cycle	1.0 \pm 0.5	1.1 \pm 0.4
Cycle abandoned	0.1 \pm 0.3	0.3 \pm 0.5
Protocole type	10	8
Stimulated cycle	0 (0.0)	0 (0.0)
Artificial cycle	10 (100)	8 (100)
Last 17 β Estradiol serum level before transfer (pg/mL)	362.3 \pm 182.5	328.3 \pm 177.5
Endometrial thickness (mm)	8.7 \pm 2.0	10.4 \pm 2.4
Duration of cycle (days)	22.9 \pm 3.2	17.5 \pm 2.7
Number of embryo transferred	10	8
1 (eSET)	8 (80.0)	3 (37.5)
2 (DET)	2 (20.0)	5 (62.5)
Stage of embryonic development (days)	10	8
D2	8 (80.0)	5 (62.5)
D3	1 (10.0)	3 (37.5)
Missing data	1 (10.0)	0 (0.0)
Quality of embryos transferred at D2	9	8
Top embryo	5 (55.6)	3 (37.5)
No top embryo	4 (44.6)	5 (62.5)
Biochemical pregnancy/total transfer	4 (40.0)	6 (75.0)
Clinical pregnancy rate/total transfer	3 (30.0)	3 (37.5)
Implantation rate at ultrasound examination on progressive pregnancy		
50%	2 (20.0)	3 (100)
100%	1 (10.0)	0 (0.0)
Ongoing pregnancy at the end of data collection /total transfer	0 (0.0)	2 (25.0)
Live birth rate/total transfer	2 (20.0)	1 (12.5)
Number of births/total transfer		
1 (singleton pregnancy)	2 (20.0)	1 (12.5)
Other pregnancy outcomes/total transfer		
Miscarriage rate	2 (20.0)	3 (37.5)

ABSTRACT

PURPOSES : We aimed to study the main characteristics and motivations of single women (SW) who have registered for sperm donation at Rouen University Hospital and to compare results of their ART cycles with those of heterosexual couples (HC).

PARTICIPANTS/MATERIALS, SETTING, METHODS : We conducted an observational, retrospective, monocentric study at the Reproductive Biology Laboratory-CECOS of the Rouen University Hospital, on all 386 SW and 67 HC registered for sperm donation between August 2021 and December 2022. Of these, 105 SW and 34 HC have started ART cycle. To ensure a more robust comparison of the ART cycle's results, we also included 41 HC who were treated for sperm donation at our centre between 2019 and the first half of 2021. We analysed all the medico-social and motivational characteristics of the women in the study, as well as the clinical pregnancy rate, the live birth rate and the miscarriage rate.

MAIN RESULTS : SW were older at the time of registration and at the start of ART cycle, and their ovarian reserve was lower than that of women in HC. Their main reasons for requesting sperm donation were the biological clock and the lack of a suitable partner to build a family project. All ART combined, there was no significant difference in clinical pregnancy or miscarriage rates between SW and HC.

CONCLUSIONS : Although SW were older and had a lower ovarian reserve, the results of their ART cycles were no worse than those of HC in our study, apart from any adjustment for age. However, these analyses need to be continued over time and space, so that they can be extrapolated and compared with the initial results of lesbian couples.

KEY WORDS : single women, heterosexual couples, sperm donation care pathway, Biology Laboratory-CECOS, Rouen University Hospital, clinical pregnancy rate, miscarriage rate.